

ROUTING SLIP
GENERATED BY: HF-40
DATE: AUG 01, 2001

FDA CONTROL NUMBER: 01 3885

TRACER #: OS #: 0725010053

DATE OF CORRESPONDENCE: 07/14/01

DATE INTO FDA: 08/01/01

TO: TOMMY THOMPSON, DEPARTMENT OF HEALTH AND HUMAN SERVICES

FROM: MARY MASTERS

SYNOPSIS: WRITER SENDS ADDENDUM TO TRAC # 01 3549, REGARDING INJURY FROM
UNAPPROVED DEVICES

LEAD OFFICE: HF-40

HOME OFFICE: HF-40

CONTACT/PHONE#: MIKELE A BRYANT 301-827-4450

COPIES: HFZ-1

HFA-305 JENNIE C BUTLER

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
HF-40	FOR YOUR INFORMATION	
HFZ-1	FOR YOUR INFORMATION	
HFA-305	NECESSARY ACTION	

Secretary's Correspondence

DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF THE SECRETARY EXECUTIVE SECRETARIAT

From: Mary Masters **OS#:** 072520010053
Organization: P.O. Box 82043 **Date on Letter:** 7/14/01
City/State: San Diego CA **Date Received:** 7/25/01
On Behalf Of: **Type:** General Public
Subject: Forwards addendum to OS#7112010053 regarding non-FDA approved prosthetics

Assigned to: FDA **Dep.ES:** Dick Eisinger
PC: Tom Kuchenberg **Date Assigned:** 7/26/01
Action Required: Info Only **Date Reassigned:**
Reply Due Date:

Info Copies To:

Interim (Y/N): No **Date Interim Sent:**

Comments:

File Index: PO-4-10 **CCC:** Elaine Gross

Ref: 01 3549

3885

July 14, 2001

Mr. Tommy Thompson
Secretary of Department of Health & Human Services
200 Independence Avenue SW
Washington, D. C. 20201

Dear Secretary Thompson

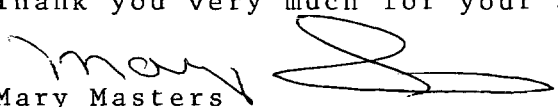
On July 5, 2001 you received a document entitled Petition
for Declaration, Pursuant to Title 21, Chapter 21, Section 1604.

Please accept the attached documents as addendum to initial
complaint. ~~have attached a complaint to~~

The do

I have not been assigned a control numbdr. I am listed under my
name, which is Mary Masters.

Thank you very much for your assistance.


Mary Masters
P. O. Box 82043
San Diego, California 92138

MR. TOMMY THOMPSON
SECRETARY OF
DEPARTMENT OF HEALTH & HUMAN SERVICES
200 INDEPENDENCE AVENUE SW
WASHINGTON, D. C. 20201

PETITION FOR DECLARATION
PURSUANT TO TITLE 21, SECTION 1604

Submitted by Claimant:
Mary Masters
P. O. Box 82043
San Diego, California 92138
Telephone: 619-462-1464

PETITION FOR DECLARATION

MARY MASTERS
Petitioner - Claimant

CALCITEK, INC.

Manufacturer - Biomaterials Supplier

RONALD W. EVASIC, D. D. S.
President of Scripps Implant Dentistry Education & Research Foundation
Biomaterials Supplier

TO THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES

Pursuant to U.S. Code as of 01/05/99

Title 21, Chapter 21, Section 1604,
Liability of biomaterials supplier

paragraph 3 (A) Administrative Procedures.

(2) (B)

PETITION FOR DECLARATION

MARY MASTERS,
Petitioner - Claimant

Creative Custom Service, Inc.
President Thomas S. Golec
President Robert L. Riley
Secretary Diane Golec
Calcitek Custom Services, Inc
Manufacturer - Biomaterials Supplier

TO THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES U.S. FOOD AND DRUG ADMINISTRATION;

Pursuant to U. S. Code as of 01/05/99

From: October, 1989 through June, 1990 Creative Custom Services
Inc. & Calcitek, Custom Services, Inc. biomaterials were sold to me the numbers
assigned to the biomaterials K840750; K900545; K900594; K900545 multiple
other biomaterials were sold to me without assigned numbers. I have evidence
in the attachments that the biomaterials were only for animal and limited controlled
human testing on the dates sold to me. I am requesting a declaration verifying
these facts.

Title 21, Chapter 21, Section 1604, Liability of biomaterials suppliers

PETITION FOR DECLARATION

MARY MASTERS,
Petitioner - Claimant
San Diego County Oral & Maxillofacial Surgery Group
President: Akbert Cutri, D.D.S M.D.
Cutri, Maw & Berger, Inc. A Dental Corporation
Albert Cutri D.D.S. M. D. & Thomas S. Golec D.D.S. M. S. Inc.
Ian Aires, B.D.S.

Biomaterials Supplier

TO THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES U.S. FOOD AND DRUG ADMINISTRATION;

Pursuant to U. S. Code as of 01/05/99

From: October, 1985 through June, 1990 I was sold biomaterials from the
above individuals and corporations. The assigned numbers to the biomaterials
are: K840750; K900545; K900594; K900545 multiple other biomaterials were
sold to me without assigned numbers. I have evidence in the attachments that the
biomaterials were only for animal and limited controlled human testing on the
dates sold to me. I am requesting a declaration verifying these facts.

Title 21, Chapter 21, Section 1604, Liability of biomaterials suppliers

Date of Sale: October, 1985 Pyrolite (trademark) Post A Carbon Coated
Dental Implant. (Pyrolite is a registered tradesman
of Intermedics, Inc. 2070 I-O 8-83), manufactured
for Calcitek, Inc. submitted under K840750

Date of Sale: October, 1985: Calcitek O Rings. submitted under K900545

Date of Sale: October, 1989: Calcitek Hydroxylapaite Crystals

Date of Sale: October, 1989 Calcitek Hydroxylapaite Granules

Date of Sale: October, 1989 Calcitek Hydroxylapaite Blocks

Date of Sale: November, 1989 Subperiosteal Calcitek Hydroxylapaite Coated

Date of Sale: October, 1989 Calcitek O Rings submitted under K900545

Date of Sale: October, 1989 Calcitek castable abutments submitted K900694

Date of Sale: March, 1990 Pyrolite Post (trademark) Post A Carbon Coated
Dental Implant, Calcitek, Inc. submitted K840750

Date of Sale: February, 1990 HA Vent Blade

Date of Sale: March, 1990 Calcitek Abutments K900594

Date of Sale: February, 1990 Calcitek O Rings: K900545

Date of Sale: June, 1990 Calcitek O Rings K900545

Date of Sale: June, 1990: Integral: Submitted under K895680

Date of Sale: July, 1990 Integral: Submitted under K895680

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ADMINISTRATIVE PROCEDURES

(A) In general Administrative Procedures

The Secretary may issue a declaration described in paragraph (2)

(B) on the motion of the Secretary or any petition by any person.

(2) (B) on the motion of the secretary or on petition by any person, after providing -

(i) notice to the affected persons; and

(II) an opportunity for an informal hearing.

(B) Docketing and final decision

Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

Petition for Declaration is being requested from the Secretary of Health & Human Resources, under Title 21, Chapter 21, Section 1604, Liability of biomaterials suppliers.

INTRODUCTION

During the period of time from October, 1989 through July, 1990, Claimant was sold Calcitek biomaterials which were only allowed to be used in animal studies and limited human investigative studies.

Claimant has sustained severe bodily injuries, past, present and future, and to date has had 11 surgeries through March, 1999, resulting from injuries received from Calcitek biomaterials. Present need for more surgeries at an additional expense of \$45,000. Claimant is filing this Petition for Declaration as her expenses for surgeries are \$107,000. . The products were represented to be FDA approved. Calcitek has denied liability for the Claimant's injuries and has falsely told the court that the products are FDA approved ; the contrary is true. The attachments proove, by a preponderance of evidence, that the products were either seized or never filed with the FDA prior to being sold to the Claimant. The products included: "HA" blocks, bio-lite blades, Integrals, castable abutments, O rings, coated subperiosteal, coated posts, all were coated with Calcitek's "HA" which was not in the range of good manufacturing practices. GMP. Calcitek, Inc. was required to register with the Secretary under section 360 of this title and Calcitek's registration number is 2023141

Title 21 - Food and Drugs
Chapter 21 - BIOMATERIALS ACCESS ASSURANCE
Section 1604 Liability of biomaterials suppliers

STATUTE

(a) In general:

Except as provided in section 1606 of this title, a biomaterials supplier shall not be liable for harm to a claimant caused by an implant unless such supplier is liable -

- (1) as a manufacture of the implant, as provided in subsection (b) of this section;
- (2) as a seller of the implant, as provided in subsection (c) of this section;
or
- (3) for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, as provided in subsection (d) of this section.

(b) Liability as manufacturer

(1) In general

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant,

(2) Grounds for liability

The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier -

(A) (i) registered or was required to register with the Secretary pursuant to section 360 of this title and the regulations issued under such section; and

(ii) Included or was required to include the implant on a list of devices filed with the Secretary pursuant to section 360 (j) of this title and the regulations issued under such section;

(B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to -

(i) register with the Secretary under 360 of this title, and the regulations issued under such section, but failed to do so; or

(ii) include the implant on a list of devices filed with the Secretary pursuant to section 360 (j) of this title and the regulations issued under such section, but failed to do so; or

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraphs (A) or (B), if the court deciding a motion to dismiss in accordance with section 1605 (c) (3) (B) (i) of this title finds, on the basis of affidavits submitted in accordance with section 1605 of this title, that it is necessary to impose liability on the biomaterials supplier as a manufacturer because the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(3) Administrative procedures

(A) In general

The Secretary may issue a declaration described in paragraph (2) (B) on the motion of the Secretary or on petition by any person, after providing -

- (i) notice to the affected persons; and
- (ii) an opportunity for an informal hearing.

(B) Docketing and final decision.

Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) Applicability of statute of limitations

Any applicable statute of limitations shall toll during the period from the time a claimant files a petition with the Secretary under this paragraph until such time as either (i) the Secretary issues a final decision on the petition, or (ii) the petition is withdrawn.

(D) Stay pending petition for declaration

If a claimant has filed a petition for a declaration with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition,

(c) Liability as seller.

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if -

(i) the biomaterials supplier -

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

(B) acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 1605 (c) (3) (B) (ii) of this title finds, on the basis of affidavits submitted in accordance with section 1605 of this title , that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) Liability for failure to meet applicable contractual requirements or specifications.

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence that -

(1) the biomaterials supplier supplied raw materials or component parts for use in the implant that either -

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for the supplying of the product; or

(B) failed to meet any specifications that were -

(i) accepted pursuant to applicable law, by the biomaterials supplier;

(ii) published by the biomaterials supplier;

(iii) provided by the biomaterials supplier to the person who contracted for such product;

(iv) contained in a master file that was submitted by the biomaterials supplier to the Secretary and that is currently maintained by the biomaterials supplier for purpose of premarket approval of medical of medical devices; or

(v) included in the submissions for purposes of premarket approval or review by the Secretary under section 360, 360c, 360e, or 360j of this title, and received cleared clearance from the Secretary if such applications were accepted, pursuant to applicable law, by the biomaterials supplier; and

(2) such failure to meet applicable contractual requirements or specifications was an actual and proximate cause of the harm to the claimant.

Calcitek was required to register pursuant to paragraph 2 (b), (A), (i) as evidenced by Petition For Reclassification of a Medical Device Under 513 (e) Endosseous Dental Implants For Prosthetic Attachment (Attachment 2).

(A) (i) registered or was required to required to register with the Secretary pursuant to section 360 of this title and the regulations issued under such section; and

(ii) included or was required to include the implant on a list of devices filed with the Secretary pursuant to section 360 (i) of this title and the regulations issued under such section:

The manufacturer Calcitek, Inc. received a letter dated August 31, 1989 from William Damaska, Director, Division of Compliance Operationd, Office of Compliance and Surveillance, Center For Devices and Radiologic Health.

On page 1, paragraph 7, Mr. Damaska:

"that the purpose of this letter is to inform you that under Section 510 (k) of the Federal Food, Drug, and Cosmetic Act (the Act) 21 U S C 360 (k) changes or modifications that could significantly affect the safety or effectiveness of the device require a notification to the Food and Drug Administration (FDA) at least (90) days prior to introduction of the changed or modified device in commercial distribution in the United States. This requirement is accomplished by the submission of a Premarket Notification - 510 - (k). The information necessary to comply with the Premarket Notification 510 - (k). The information necessary to comply with the Premarket Notification 510 (k)) requirement is found in 21 CFR Part 807, Subpart E. Premarket Notification (copy enclosed).

On page 1, paragraph 8, Mr. Damaska:

"We would appreciate a response within 30 days describing action you have taken to achieve compliance with the Act or providing information which you believe substantiates your decision that a 510 (k) is not required." (Attachment 3)

On July 10, 1998, Mr. Richard LaRiviere was deposed for the State of California County of Range, California, Case No. 747549 entitled Connie Bentele vs. Calcitek, Inc. Mr. LaRiviere was asked the question page 115 paragraph 2: line 7-11

A Back in 1985-1989, when this product was first introduced, you simply had to have the evidence on file. Not until 1989, when the claims were challenged, did we realize or did we find out that the claims were not considered substantially equivalent, or substantiated. We believed we were in compliance."

page 116, lines 3-4

Q Despite your belief that you were in compliance, the FDA determined otherwise; correct?

Page 116: line 5

A Yes

page 116: lines 18-20

Q However, based on the FDA's ultimate determination, is it your understanding that what was on file ultimately was determined to not be adequate?

page 117: lines 11-21

Q You testified that Calcitek had placed certain information on file with the FDA with regards to the claims that were placed on the brochures.

A Yes

Q You testified that Calcitek was under the impression that those claims were sufficient,

A Yes.

Q The FDA ultimately determined that they were insufficient; correct?

A Correct.

The foregoing evidence is Attachment 4.

Title 21; Chapter 21; Section 1604; paragraph 3 (A) Administrative Procedures

(A) In general

The Secretary may issue a declaration described in paragraph (2) (B) on the motion of the Secretary or any petition by any person.

Claimant is filing this petition pursuant to paragraph 3 (A) Administrative Procedures.

(c) Liability of seller

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if -

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

Calcitek held title to the Integral implant a tradesman for Calcitek, Inc. See

Biointegration Integral (Attachment 5) It was falsely advertised as being FDA approved.

(2) (B) on the motion of the secretary or on petition by any person, after providing -

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) Docketing and final decision

Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) Applicability of statute of limitations

Any applicable statute of limitations shall toll during the period from the time a claimant files a petition with the Secretary under this paragraph until such time as either (i) the Secretary issues a final decision on the petition, or (ii) the petition is withdrawn.

(D) Stay pending petition for declaration

If a claimant has filed a petition for a declaration with respect to a defendant, and the Secretary Has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

(c) Liability as seller

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if-

(1) the biomaterials supplier-

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

(B) acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant; or

HISTORY

In 1976, P.A. 442 as amended, the Department of Justice filed suit against Dr. Evasic in the State of Michigan. Consent Order dated January 17, 1983; Stipulation dated: November, 30, 1982, First Amended Complaint, Dated March 4, 1982 and Complaint Dated October 27, 1977.

In 1987, Dr. Ronald W. Evasic formed a nonprofit California corporation entitled The Scripps Implant Dentistry Education and Research Foundation (SIDERC), located at Scripps Torrey Pines Campus, La Jolla, California. (Exhibit 1) At that time Dr. Evasic was not a California dentist, as he did not receive his California dental license until August 3, 1990 and the license is no longer valid in the State of California License No. 38676.

The corporation President and Director was Dr. Ronald W. Evasic who at that time was licensed by the State of Michigan License No. -29-01-008170, Expired 8/31/93 and the State of Oklahoma. Dr. Evasic conducted dental implant training courses through his corporation in California and Oklahoma. At that time, Dr. Evasic resided at 2419 Foilage Drive, Ada, Oklahoma, 94820. The dentists who enrolled in the courses were told to mail their checks to Dr. Evasic's residence in Oklahoma; however, they were not told that they were mailing their checks to Dr. Evasic's residence, they were told that they were mailing their checks to Scripps Implant Dentistry Center. Each dentist mailed a check for \$7,500.00. (Exhibit 2).

In 1988, Dr. Evasic hired Dr. Thomas Golec, a California dentist to teach subperiosteal dental implant training through Dr. Evasic's corporation. Dr. Golec was in private group practice and he was also a research dentist for Calcitek, Inc.


The materials used in the dental implant courses were Calcitek, Inc. products which were mailed to the dentists from Texas and from Calcitek, Inc. in Carlsbad, California.

In 1988, Calcitek, Inc. was a California corporation owned by InterMedica, Inc. a California corporation, who then became a Texas corporation.

In August, 1989, Calcitek, Inc. was purchased by Sulzer medica, Inc. of Winterthur, Switzerland. At a later date Sulzer medica, Inc. moved from Switzerland to the State of Texas.

Conclusion

The foregoing declsrations are requested to be sent to the
Claimant at: Mary Masters, P. O. Box 82043, San Diego, California
92138. If you have any questions, please contact me.: Telephone:
619-462-1464



Mary Masters, Claimant

Mary Masters
P. O. Box 82043
San Diego, California 92138

619-462-1464

In Pro Per

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN DIEGO.

Mary Masters

Plaintiff

v

Robert L. Riley, an Individual,
Sulzer Calcitek, Inc., a corporation;
Ian Aires, D.D.S, an Individual
Cutri, Maw & Berger Inc., a
dental corporation (dba San Diego
County Oral & Maxillofacial
Surgery Group) Ralph B. Maw
D.D.S., a professional corporation
Creative Custom Services, Inc.
a corporation, Ronald Evasic,
D.D.S., an Individual; Scripps
Implant Dentistry Education
* Research Center, Diane Golec,
an individual

Defendants

I declare the following:

1. I filed a complaint similar in its entirety with the United States

District Court, Southern District of California. I was denied hearing.

as it was decided that although the biomaterials are under the federal jurisdiction, the issues are State issues. (Attachment 1).

2. I want to file a new lawsuit as a Plaintiff as follows: I am injured from the biomaterials sold to me from October, 1985 through July, 1990. I have filed a Petition For Declaration, Pursuant to Title 21, Chapter 21, Section 1604 with Mr. Tommy Thompson, Secretary of the Department Of Health & Human Services, 200 Independence Avenue, SW, Washington, D. C. 20201.

The Petition For Declaration was received July 5, 2001. (Attachment 2 & enc.) The biomaterials sold to me had the following control numbers: K840750; K895680, K900545; K900594; K900545. The remainder of the biomaterials used in my treatment plan were never filed with the Federal, Food and Drug Administration. In addition, the Calcitek Biolite (trademark) Carbon Coated Metal Dental Implant, which was submitted under K840750 for a name change to:

Calcitite Hydroxylapatite Coated Dental Implant was seized prior to being sold to me. The Pyrolite (trademark) Post A Carbon Coated Dental Implant, (Pyrolite is a registered trademark of Intermedics, Inc. 2070 I-) 8-83), manufactured by Intermedics, Inc. for Calcitek, Inc.

1 3. I filed Case No. 689457, in pro per, State of California, County of
2 San Diego, Superior Court, entitled Masters v. Aires. (Dr. Aires joined
3 Estate of Thomas Golec, D.D.S) The defendants: Ian Aires, B.D.S,
4 Estate of Thomas Golec, D.D.S. and Calcitek, Inc and their attorneys
5 of record Theresa Twomey, Robert Harrison and Thomas Dymott,
6 falsely told the court that the biomaterials sold to me were FDA
7 approved. (Attachment)
8

9 4. Attachment 3 is declaration by Robert L. Riley, an employee of
10 Calcitek Custom Services, Inc developed a "plasma spraying
11 technique" for hydroxylapaite attachment to metals. Either Mr. Riley
12 or another employee of Calcitek Custom Services, Inc. "plasma
13 sprayed" the subperiosteal which was sold to me during Dr. Evasic's
14 dental implant training courses at The Scripps Implant Dentistry
15 Education and Research Foundation (SIDERC). The subperiosteal
16 and "HA" blocks were implanted into my jawbone by Dr. Golec,
17 D.D.S. who had been hired by Dr. Evasic to teach the subperiosteal
18 courses at SIDERC. (In October, 1985, February, 1990,
19 June, 1990 and July, 1990, the biomaterials were implanted at the
20
21
22
23
24

San Diego County Oral & Maxillofacial Surgery Group, President

Dr, Akbert Cutri.

From November, 1989 through Feb, 1992, Dr. Aires worked with Dr. Golec in my treatment plan and they decided to use Calcitek viomaterials whose control numbers are: K840750; K895680, K900545; K900594; K900545 and they did not disclose that these products were investigativ or seized at earlier dates..

On April 11, 1989, Dr. Barry Sands, Department of Health & Human Services, Biomedical Engineer told Calcitek, Inc.

(memorandum attached to Petition for Declaration)

“Unapproved Indications for use of Calcitek Hydroxylapaite
Hydroxylapaite: Calcitek is presently marketing an endosseous
implant for bone filling and augmentation with the indication for
use with dental implants. This indication for use has never been
reviewed by DOED. In addition, we would find that this
indication for use would warrant animal and clinical trials to
determine its safety and effectiveness-----”

5. Case No. 689457” In November, 1996, I received a FOIA package which included Petition for Reclassification of a Medical Device, Under Section 513 (e) submitted to the Department of Health & Human Services U.S. Food and Drug Administration. The essence of

1 the petition was a request to allow the biomaterials to be marketed
2 without firstly obtaining premarket approval (PMI). The petition was
3 submitted in December, 1989. The petition was denied by the FDA.

4 I submitted this petition to Judge Thomas O. La Voy and he
5 would not accept this petition, as he said that it was "untimely".

6 5. I had a trial by jury in January, 1994, in the State of California
7 County of San Diego entitled: Masters v. Estate of Thomas Golec,
8 D.D.S. Dr. Albert Cutri falsely told the court that he had heard Dr.
9 Golec give me informed consent for the biomaterials through their
10 thin office walls. His false testimony denied my right to due process.
11 Diane Golec testified on behalf of the Estate of Dr. Golec, and she
12 testified that she did the paper work for Dr. Golec. She was therefore
13 aware that the biomaterials were not FDA approved.

14 Dr. Evasic testified on behalf of the Estate of Dr. Golec and Attorney
15 Sussman failed to discover that he had sold me biomaterials through
16 his dental implant school SIDEC and that he was a not a dentists
17 licensed by the State of California at that time. . The foregoing facts
18 place a cloud over the validity of the trial, as had :a) Attorney Sussman
19 told the jury that the biomaterials were not FDA approved, the

outcome would have been different; b) If Dr. Cutri had not falsely told
the court that the I had been given verbal informed consent for "HA",
the outcome would have been different; c) If Attorney Sussman had
told the jury that Dr. Evasic had distributed these biomaterials
to Dr. Golec during his dental implant training courses at SIDEC,
the outcome would have been different; d) if Dr. Aires had not
testified against me and violated my right to due process, the outcome
would have been different; e) if Diane Golec had not testified that her
husband was highly recognized in the field of dental implantology, and
failed to disclose that the societies who recognized him were not
recognized by the State of California, the outcome would have
been different; f) If Attorney Sussman had told the jury that Dr. Golec
was doing investigative studies with biomaterials which were for
animal studies and limited clinical investigations, the outcome would
have been different. g) If the defense attorney Robert Harrison, had
not falsely blamed God for the injuries to my mouth, the outcome
would have been different; h) if the defense attorney Robert Harrison
had not falsely told the court that I had two teeth in my mouth, the out
come would have been different; the truth is I had twenty-six.

1 if the defense attorney Robert Harrison had not falsely told
2 the court, on the day of deliberation, that the day was his birthday,
3 there would have been one less lie for the jury to hear. If Robert
4 James, D.D.S., had not falsely told the court that I had a jaw deformity
5 prior to being treated by Drs.Evasic, Golec, Aires and Berger, the
6 outcome would have been different; if 20 pages of my patient records
7 had not been removed, the outcome would be different.
8

9 6. On or about November 21, 1991, Dr. Thomas S. Golec, Mr. Riley
10 and Diane Golec were incorporated under the name of Creative
11 Custom Services, Inc., at 455 N. Twin Oaks Valley Rd., San Marcos,
12 California 92069, and the "HA" coating was at this location.
13

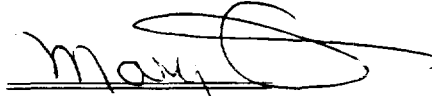
14 Biomaterials which had failed were coated and repaired with more
15 biomaterials., (Attachments 6)
16

17 7. This lawsuit is not filed for the purpose of harassment or delay.
18

19 Wherefore, I request an order permitting me to file a new lawsuit in
20 this court.
21

22 I declare under the laws of perjury of the State of California that the
23 foregoing is true and correct.
24

25 July 14, 2001

26 
27 Mary Masters
28 Plaintiff In Pro Per

Mary Masters
P. O. Box 82043
San Diego, California 92138

619-462-1464

In Pro Per

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN DIEGO

Mary Masters

Plaintiff

v

Robert L. Riley, an Individual,
Sulzer Calcitek, Inc., a corporation;
Ian Aires, D.D.S, an Individual
Cutri, Maw & Berger Inc., a
dental corporation (dba San Diego
County Oral & Maxillofacial
Surgery Group) Ralph B. Maw
D.D.S., a professional corporation
Creative Custom Services, Inc.
a corporation, Ronald Evasic,
D.D.S., an Individual; Scripps
Implant Dentistry Education
& Research Center, Diane Golec,
an individual

Defendants

Case No.

Motion In Support
Of Order (Order
Requested)

Title 21; Chapter 21
Section 1604

Hearing Date:

Time:

Judge

Date of Filing Action

Trial Date:

I declare the following:

1. I filed a complaint similar in its entirety with the United States

District Court, Southern District of California. I was denied hearing.

1.

Prefiling Order.

INTRODUCTION

1 United States District Court, Southern District of California
2
3 Case No. 99 CV 2215K RBB was filed within 1 year of my receiving
4 and understanding newly obtained evidence proving that the
5 biomaterials sold to me were either seized, never filed with the FDA
6
7 A hearing has been denied on the ground that even though the
8 biomaterials are under the federal jurisdiction, there is no federal
9 question. This case therefore is in the jurisdiction of the State of
10 California. The complaint (attached) is similar in its entirety to the
11 complaint filed in the District Court.
12
13

14 From October, 1985 through November, 1992, Calcitek, Inc.
15 Intermedica Inc., Creative Custom Services, Inc.; Calcitek Custom
16 Services, Inc. biomaterials were sold to me by Ronald Evasic, D.D.S,
17 President of The Scripps Implant Dentistry Education & Research
18 Foundation; and Cutri, Maw & Berger, Inc. A Dental Corporation,
19 Albert Cutri, D.D.S. M.D & Thomas S. Colec D. D. S. M. S Inc.
20 Ralph B. Maw, A Professional Corporation doing business as San
21 Diego County Oral & Maxillofacial Surgery Group and Ian Aires,
22 B.D.S. who planned my treatment program with Thomas S. Golec,
23
24
25
26
27
28

1 The biomaterials had the following assigned numbers: K840750;
2 K7896680; K900594; K900545. I have evidence in the attachments
3 that these products were not FDA approved on the dates
4 that they were sold to me. Other biomaterials were sold to me which
5 were seized prior to the sale date or never filed with the FDA.

6 Since June, 1995, in every case I have filed in the State of California,
7 County of San Diego, Superior Court, each defendant has falsely
8 told the court that the biomaterials were FDA approved.
9

10 I have filed a Petition for Declaration pursuant to Title 21 Chapter
11 21, Section 1604 with Secretary Tommy Thompson, Department of
12 Health & Human Services, 200 Independence Avenue SW,
13 Washington, D.C. Section 1604 was enacted January, 1999.
14 Title 21, Section 1604 defines the liability of the biomaterials
15 manufacturer and the biomaterials suppliers.
16
17

18 POINTS & AUTHORITIES

19 Please see Petition for Declaration submitted to the Department
20 of Health & Human Resources for the detailed explanation of Title
21 21 Chapter 21 Section 1604. (Attached)
22
23
24

CONCLUSION

1 This motion is made in support of prefiling order. Declaration,
2 Petition for Declaration and Proposed Complaint are attached.

3 This motion is being made to request that all of the money which
4 I have paid for the biomaterials be returned to me; that all of the past,
5 present, and future emergency and corrective surgery expenses be
6 returned to me; that the laboratory fees, biopsies, bone scans, cat scans,
7 x-rays, consultant fees be returned to me. This is a total of \$108,450.
8

9
10 In addition, this request is for the biomaterial manufacturers, to
11 reimburse me for my attorney fees to: Attorneys Terry Traktman and
12 Michael Quevedo, and their assistants, legal clerks, cell telephone
13 calls, copying fees, filing fees and process fees, according to proof,
14 as Title 21, Chapter 21, Section 1604 provides for the liability of the
15 manufacturers and Section 1604 was enacted at the time that I
16 paid for these legal expenses.
17

18
19 For the foregoing reasons, I am requesting a Prefiling Order.
20

21 July 15, 2001

22 Respectfully submitted,

23
24 

25 Mary Masters, Plaintiff
26 In Pro Per
27

PROOF OF SERVICE

I, Mary Masters declare, that I am over the age of eighteen years and that I am a party to this action. I served the following documents on July 16, 2001 on the following parties: There is no case number at this time.

Motion For Order (Order Requested) Title 21; Chapter 21, Section; 1605
Petition for Declaration: Pursuant to Title 21; Chapter 21; Section 1064

Robert Harrison, Esq.
Thomas Dymott, Esq,
Hugh Mc Cabe, Esq.
1010 Second Avenue, Suite 2500
San Diego, California 92101

Ronald Evasic, D.D.S an individual
President of: The Scripps Implant Dentistry Education and Research Foundation
c/o Robert Harrison, Esq.

Diane Golec, an individual c/o
Robert Harrison, Esq.

Cutri, Maw & Berger, Inc. A Dental Corporation
San Diego County Oral & Maxillofacial Surgery Group
Albert Cutri, M. D. D. D.S.
c/o Attorney Hugh McCabe, Esq.

Calcitek, Inc. Robert L. Riley, Calcitek Custom Services, Inc.; Creative Custom Services, Inc. c/o Attorneys Thomas Dymott & Hugh McCabe


Creative Custom Services, Inc., A California Corporation
c/o Garth O. Reid Esq., 310 East Second Avenue, Escondido, Ca. 92025

Brian Rawers, Esq.; Medell & Rawers: 1010 C St., Suite 1515, San Diego, Ca. 92101: Attorney for Dr. Ian Aires

I declare under the laws of the State of California under the penalty of perjury the foregoing is true and correct

July 15, 2001
P. O. Box 82043
San Diego, Ca. 92138

Mary Masters



40 10 10 31 7PM

Mary Masters
P. O. Box 82043
San Diego, California 92138

619-462-1464

In Pro Per

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN DIEGO

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Plaintiff

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dental corporation (dba San Diego
County Oral & Maxillofacial
Surgery Group) Ralph B. Maw
D.D.S., a professional corporation
Creative Custom Services, Inc.
a corporation, Ronald Evasic,
D.D.S., an Individual; Scripps
Implant Dentistry Education
& Research Center, Diane Golec,
an individual

Defendants

Case No.

Complaint For Damages
For Personal Injuries
(Negligence Per Se,
Fraud, Negligence,
Breach of Fidiciary
Duty; Dental Malprac-
tice, Gross Negli-
gence; Negligent
Infliction of Emotional
Distress, Intentional
Infliction of Emotional
Distress, Strict Liabil-
ity, Breach of Warranty
Breach of Contract,
Breach of Covenant
of Good Faith and
Fair Dealing; Violation
of Title 21, Chapter 21,
Sec. 1604

I declare the following:

1. I filed a complaint similar in its entirety with the United States

District Court, Southern District of California. I was denied hearing.

1.

1 of California.

2 2. The true names and capacities, whether individual,
3 corporate, partnership, associate or otherwise, of Defendants DOES
4 1 through 30, inclusive, are presently unknown to Plaintiff who
5 therefore sues said Defendants by such fictitious names. 3.

6 Plaintiff is informed, believes, and thereon alleges that
7 each of the Defendants designated herein as a DOE is responsible
8 in some manner for the events and happenings herein referred to
9 and legally caused the damages herein alleged. Plaintiff will
10 seek leave of this Court to amend the respective pleadings to set
11 forth the true names and capacities of said factitiously named
12 Defendants when their identities become known to Plaintiff.

13 4. Plaintiff is informed, believes and thereon alleges
14 that, at all times mentioned herein, Defendant ROBERT L. RILEY
15 (MR. RILEY) was an individual and a resident of the County of San
16 Diego of the State of California. Plaintiff is further informed,
17 believes and thereon alleges that, at all times mentioned herein,
18 MR. RILEY was a Director and Shareholder of CALCITEK, INC., and

19

20 5. On information and belief Plaintiff alleges Defendant
21 SULZER CALCITEK, INC. (CALCITEK), is a corporation, organized and
22 operating under the laws of the State of California with its
23 principal place of business in Carlsbad, California.

24 6. Plaintiff is informed, believes and thereon alleges that
25 the background of CALCITEK is as follows: CarboMedica, Inc.
26 (CarboMedica) was the alter ego of Calcitek, Inc. and was created,
27 owned, and operated by Michael Jarcho, Phd. On or about 1985,

28

1 InterMedica, Inc. (InterMedica) purchased CarboMedica and Michael
2 Jarcho, Phd. became president of Calcitek, Inc.. On or about 1988
3 Calcitek, Inc. was purchased by InterMedica, Inc. (InterMedica).
4 In late 1989, InterMedica, Inc. and Calcitek, Inc. were both
5 purchased by SULZERmedica, Winterthur, Switzerland (SULZERmedica).
6 On or about January 22, 1997, the name was changed to "Sulzer
7 Calcitek, Inc."

8 7. Plaintiff is informed, believes, and thereon alleges
9 that, CALCITEK continues to produce the same products as it did
10 prior to its purchase by SULZERmedica in 1989, which includes
11 hydroxylapatite ("HA") particles and various HA coated endosseous
12 dental implants that are set forth below in detail.

13 8. At all times mentioned herein, Defendant IAN AIRES,
14 D.D.S. (DR. AIRES) was an individual and a resident of the County
15 of San Diego of the State of California. DR. AIRES co-treated
16 Plaintiff with Dr. Thomas Golec from 1989 through 1992.

17 9. On information and belief Plaintiff alleges Defendant
18 CUTRI, MAW & BERGER, INC., a dental corporation (dba, SAN DIEGO
19 COUNTY ORAL & MAXILLOFACIAL SURGERY GROUP ("SURGERY GROUP")) was a
20 corporation, organized and operating under the laws of the State
21 of California with its principal place of business in California.

22 10. Plaintiff is informed, believes and thereon alleges that
23 CUTRI, MAW & BERGER, INC. was incorporated on or about March 25,
24 1974 and dissolved on or about May 31, 1990; during which time
25 this Defendant treated Plaintiff as set forth herein. Plaintiff
26 is further informed, believes and thereon alleges that the
27 following dentists were members of the SURGERY GROUP while
28

1 Plaintiff was its patient: A.A. Cutri, D.D.S., M.D. (president of
2 the group); T.S. Golec, D.D.S., M.S.; Maw, D.D.S.; J.S. Berger,
3 D.D.S., M.D.; F.W. Hammond, D.D.S.

4 11. Plaintiff is further informed, believes and thereon
5 alleges that at all relevant times herein mentioned (except, as
6 otherwise stated), dentists A.A. Cutri, D.D.S., M.D.; T.S. Golec,
7 D.D.S., M.S.; Maw, D.D.S.; J.S. Berger, D.D.S., M.D.; F.W.
8 Hammond, D.D.S. and DOES 1-5 were doing business under the name of
9 CUTRI, MAW & BERGER, INC., a dental corporation (dba, SAN DIEGO
10 COUNTY ORAL & MAXILLOFACIAL SURGERY GROUP). And, at all times
11 herein mentioned, CUTRI, MAW & BERGER, INC., a dental corporation
12 (dba, SAN DIEGO COUNTY ORAL & MAXILLOFACIAL SURGERY GROUP;
13 dentists A.A. Cutri, D.D.S., M.D.; T.S. Golec, D.D.S., M.S.; Maw,
14 D.D.S.; J.S. Berger, D.D.S., M.D.; F.W. Hammond, D.D.S.; and DOES
15 1-5 were the agents and employees of each other and, in doing the
16 things hereinafter alleged, were acting in the scope of their
17 agency and employment and with the permission and consent of the
18 principal and/or employer.

19 12. On information and belief Plaintiff alleges Defendant
20 RALPH B. MAW D.D.S., was a professional corporation, organized and
21 operating under the laws of the State of California with its
22 principal place of business in California.

23 13. Plaintiff is informed, believes and thereon alleges that
24 RALPH B. MAW D.D.S. was incorporated on or about September 18,
25 1989 and dissolved on or about June 12, 1992; during which time
26 this Defendant treated Plaintiff as set forth herein. 14.

27 Plaintiff is informed, believes and thereon alleges that the
28

1 following dentists were officers, directors and worked for RALPH
2 B. MAW D.D.S.: T.S. Golec, D.D.S., M.S.; Ralph Maw, D.D.S.; who
3 at all relevant times mentioned herein (except as otherwise
4 stated) were doing business under the name of RALPH B. MAW D.D.S..

5 15. At all times herein mentioned, RALPH B. MAW D.D.S.; T.S.
6 Golec, D.D.S., M.S.; Maw, D.D.S.; and DOES 6-10 were the agents
7 and employees of each other and, in doing the things hereinafter
8 alleged, were acting in the scope of their agency and employment
9 and with the permission and consent of the principal and/or
10 employer.

11 16. On information and belief Plaintiff alleges Defendant
12 CREATIVE CUSTOM DESIGN, INC, (CREATIVE CUSTOM DESIGN) was a
13 corporation, organized and operating under the laws of the State
14 of California with its principal place of business in California.

15 This corporation was incorporated on or about 1991 and dissolved
16 on or about 1997; during which time this Defendant treated
17 Plaintiff as set forth herein. On information and belief
18 Plaintiff alleges that CREATIVE CUSTOM DESIGN, at all times
19 mentioned herein was the alter ego of CALCITEK, and on or about
20 1990 purchased the subperiosteal division of CALCITEK. Also, on
21 information and belief, Plaintiff alleges that, at all times
22 mentioned herein, Creative Custom Services, Inc. was owned and operated by
23 Dr. Golec, Diane Golec, and MR. RILEY; and that these individuals
24 were Directors and Officers of this corporation.

25 17. At all times herein mentioned
26 T.S. Golec, D.D.S., Diane Golec, MR. RILEY and DOES 6-10 were the
27 agents and employees of each other and, in doing the things
28

1 hereinafter alleged, were acting in the scope of their agency and
2 employment and with the permission and consent of the principal
3 and/or employer.

4 18. At all times mentioned herein, Defendant RONALD EVASIC,
5 D.D.S. (DR. EVASIC), is an individual and a resident of the County
6 of San Diego of the State of California.

7 19. On information and belief Plaintiff alleges Defendant
8 SCRIPPS IMPLANT DENTISTRY EDUCATION & RESEARCH CENTER (SCRIPPS
9 IMPLANT DENTISTRY) is an unknown business entity, organized and
10 operating under the laws of the State of California with its
11 principal place of business in California.

12 20. On information and belief, Plaintiff alleges that, at
13 all times mentioned, DR. EVASIC was doing business under the name
14 of SCRIPPS IMPLANT DENTISTRY EDUCATION & RESEARCH CENTER. DR.
15 EVASIC and SCRIPPS IMPLANT DENTISTRY EDUCATION & RESEARCH CENTER
16 are not affiliated, directly or indirectly, with any of the
17 internationally acclaimed health care facilities located in La
18 Jolla, California known as the Scripps Institutions of Medicine
19 and Science.

20 21. At all times herein mentioned, DR. EVASIC, SCRIPPS
21 IMPLANT DENTISTRY and DOES 11-15 were the agents and employees of
22 each other and, in doing the things hereinafter alleged, were
23 acting in the scope of their agency and employment and with the
24 permission and consent of the principal and/or employer.

25 22. Each of the Defendants named herein are also
26 collectively referred to as "Defendants."

27 23. Each of the Defendants named herein that alleged to be
28

1 licensed to practice dentistry are also collectively referred to
2 herein as "Defendant dentists."

3 24. At all times herein mentioned, all of the Defendant
4 dentists mentioned herein, were dentists licensed to practice
5 dentistry under the laws of the State of California and were
6 engaged in the practice of dentistry in California.

7 25. Plaintiff is informed, believes and thereon alleges that
8 she was injured for the following reasons: (1) by CALCITEK
9 products that were not approved by the Federal Food and Drug
10 Administration (FDA); (2) by negligent dentists since they used
11 medical devices that were not approved by the FDA; and (3) by
12 ongoing material misrepresentations that Plaintiff's dental
13 implants are FDA approved and by false advertisements .

14 26. Plaintiff is informed, believes and thereon alleges that
15 at all times mentioned herein, CALCITEK manufactured products that
16 by law are deemed "medical devices" requiring FDA approval prior
17 to marketing. Plaintiff is further informed and believes and
18 thereon alleges that the following are some of the medical devices
19 manufactured by CALCITEK: (a) "Calcitite", (b) "Integral", (c)
20 "Hydroxylapatite Coated Endosseous Dental Implants", (d)
21 "Biointegrated Dental Implant Systems", (d) "Calcitite
22 Nonresorbable Hydroxylapatite Bone Grafting Material", (e)
23 "Calcitek Integral Omniloc System", and (f) "Bio-Blade". --- The
24 above mentioned medical devices, as well as the name "Calcitek"
25 are all registered trademarks of CALCITEK.

26 27. Plaintiff is informed, believes and thereon alleges
27 that, at all times mentioned herein, Calcitite was manufactured by
28

1 CALCITEK, in many different forms such as in the following forms:
2 "crystals," "plasma," "particles," "granulars," and "blocks."
3 Other common terminology used herein that refers to Calcitite and
4 its different forms are as follows: "HA grafting," "HA plasma,
5 "HA block," "HA filler," and "Ceramic HA,"; (collectively referred
6 herein as "Calcitite")

7 28. Plaintiff is informed, believes and thereon alleges
8 that, some of the Calcitite-coated devices implanted in
9 Plaintiff's jaws include: posts, castable abutments, o-rings,
10 Integrals, blade, and Bio-Blade. Plaintiff is further informed,
11 believes and thereon alleges that all of the medical devices
12 implanted in her mouth were coated with Calcitite, all were
13 manufactured by CALCITEK, and all were sold to her.

14 29. Plaintiff is informed, believes and thereon alleges that
15 although HA is naturally produced in the body, CALCITEK's versions
16 of HA are different from the natural HA as it is made with heavy
17 metals in different proportions and ratios than that of natural HA
18 and the FDA determined that CALCITEK's HAs do not meet the minimum
19 standards.

20 30. On information and belief, the FDA informed CALCITEK, in
21 a letter dated April 13, 1984, that CALCITEK's 510(k) submission
22 (No. K840750), regarding the intent to market their HA coated
23 endosseous dental implants (Calcitite-coated dental implants), was
24 approved as the FDA's determination, after reviewing the
25 notification, was that the medical device is "substantially
26 equivalent" to devices marketed in the interstate commerce prior
27 to May 28, 1976, the enactment date of the Medical Device
28

1 Amendments.

2 31. Plaintiff is informed, believes and thereon alleges that
3 the FDA also informed CALCITEK, in the above April letter, that it
4 gave CALCITEK approval to market the device subject to the general
5 control provisions of the Federal Food, Drug, and Cosmetic Act
6 ("Act") until such time as the device has been classified under
7 Section 513 of the Act; at that time, if the device is classified
8 into either Class II (Performance Standards) or Class III
9 (Premarket Approval), it would be subject to additional controls;
10 the general controls presently include regulation on annual
11 registration, listing of devices, good manufacturing practice,
12 labeling, and misbranding and adulteration provisions of the Act.

13 32. On information and belief, plaintiff alleges that
14 significantly, in the above April 13, 1984 letter, the FDA
15 informed CALCITEK that this letter did not in any way denote
16 official FDA approval of the device or its labeling. It further
17 ~~states that any representation that creates an impression of~~
18 ~~official approval of this device because of compliance with the~~
19 ~~premarket notification regulations is misleading and constitutes~~
20 ~~misbranding.~~ Plaintiff is informed, believes and thereon alleges
21 that CALCITEK has continuously been doing the very thing the FDA
22 warned against and that is representing their completion of the
23 premarket notification regulations as the FDA's official approval
24 of the medical device. On information and belief, Plaintiff
25 alleges that CALCITEK's 510(k) submission for premarket
26 notification is based on their on fraudulent certification that
27 the device should be grandfathered in since it is "substantially
28

1 equivalent" to devices marketed prior to May 28, 1976.

2 33. On or about September 1985, a post broke in Plaintiff's
3 root canaled tooth located in her lower left jaw. She was
4 referred by DR. AIRES to Dr. Golec who was an oral surgeon.
5 Plaintiff is informed, believes and thereon alleges that, at all
6 times mentioned herein both DR. AIRES and Dr. Golec were
7 shareholders of CALCITEK and CarboMedica as well as clinicians and
8 research dentists for CALCITEK and CarboMedica.

9 34. On or about September 1985, Dr. Golec told Plaintiff
10 that the blade he would implant in her mouth was "state-of-the-art
11 and better than nature dental implant" and no warning was given to
12 her regarding the blade. On or about October 1985, Dr. Golec
13 surgically implanted the blade.

14 35. Plaintiff is further informed, believes and thereon
15 alleges the 1985 blade was manufactured by Carbomedica in
16 conjunction with CALCITEK and was coated with CALCITEK's
17 Calcitite. Plaintiff was charged and paid \$500.00 (Five Hundred
18 Dollars) for the blade implant.

19 36. Plaintiff is informed, believes and thereon alleges that
20 once the Calcitite, Calcitite coating regardless of the form is
21 exposed to Plaintiff's oral cavity it was dissolved by acidic
22 fluids of the saliva and infection with subsequent bone loss
23 became inevitable. Consequently, the blade implant (as well as
24 all of CALCITEK's products implanted in Plaintiff's mouth)
25 corroded Plaintiff's jaw bones causing chronic pain and gagging
26 when she chews food.

27 37. Plaintiff is informed, believes and thereon alleges
28

1 that, on or about April 11, 1989, the FDA informed CALCITEK they
2 were violating the Act and that they were not to market their
3 Calcitite (which includes, amongst others, HA grafting materials,
4 HA crystals, HA blocks) before first testing on animals and
5 performing successful clinical trials. Plaintiff is further
6 informed, believes and alleges that, at all times mentioned
7 herein, CALCITEK, DR. AIRES, Dr. Golec and MR. RILEY have
8 declared, directly and/or indirectly and under penalty of perjury,
9 that Plaintiff was not used in any animal or clinical trials.

10 38. Plaintiff is informed, believes and thereon alleges that
11 CALCITEK had evaded the FDA approval process up to this point by
12 falsely certifying that their products were "substantially
13 equivalent" to devices marketed in interstate commerce prior to
14 May 28, 1976, the enactment date of the Medical Device Amendments.

15 39. On or about August 31, 1989, the FDA sent CALCITEK a
16 letter wherein the FDA informed CALCITEK that it had come to their
17 ~~attention that CALCITEK made or is considering making the~~
18 following changes or modifications to the Integral's labeling
19 claims: (1) "This coating permits bone to actually bond with the
20 implant surface." (2) "Histological studies demonstrate why
21 Calcitite-coated implants may perform better than uncoated
22 implants." (3) "...Calcitite-coated implants covers a greater
23 percentage of implant surface. Plus there are virtually no
24 fibrous tissue elements between the bone and the implant."
25 Plaintiff is informed, believes and thereon alleges that CALCITEK
26 did in fact make the above 3 labeling claims regarding the
27 Integral.

28

1 distribution of the offending literature containing the above
2 mentioned marketing claims and any interim use of literature
3 containing any of the claims was suppose to contain the words
4 "INVESTIGATIONAL CLAIMS UNDER REGULATORY REVIEW" clearly printed
5 on the marketing document.

6 44. On information and belief, Plaintiff alleges that on or
7 about September 19, 1989, Dave Segerson (the Deputy Director of
8 the DOED) held a meeting with CALCITEK regarding unsubstantiated
9 product claims of the Integral. Present at the meeting for
10 CALCITEK were Mr. LaRiviere and Floyd Larson. Mr. Casper Uldrike,
11 OCS/DCO and Mr. Barry Sands, ODE/DOED explained that the Integral
12 was considered misbranded and adulterated and was subject to
13 seizure.

14 45. On or about September 22, 1989, the FDA sent a letter to
15 CALCITEK informing them that the new Premarket Notification for
16 the Integral, under Section 510(k) has been assigned the document
17 control number (DC No. K895680) and that CALCITEK must wait 90
18 days after 9/20/89 (the received date by the FDA) or until receipt
19 of a "substantially equivalent" letter before placing the Integral
20 into commercial distribution. Calcitek was also warned by the
21 FDA, in the September 22, 1989 letter, that the FDA is able to
22 continue the review of a submission beyond the ninety day period
23 and might conclude that the device is not substantially
24 equivalent. A "not substantially equivalent" device may not be in
25 commercial distribution without an approved premarket approval
26 application or reclassification of the device. The FDA,
27 therefore, recommended that CALCITEK not market the Integral
28

1 40. In the above FDA letter, dated August 31, 1989, the FDA
2 goes on to say the above changes constitute significant changes
3 (as described in 21 CFR § 807.81(b) of the Act) in the Integral.
4 That, under Section 510(k) (of the Act at 21 U.S.C. § 360(k))
5 changes or modifications that could significantly affect the
6 safety or effectiveness of the device require a notification to
7 the FDA at least 90 days prior to introduction of the changed
8 modified device in commercial distribution in the United States.
9 This requirement is accomplished by the submission of a Premarket
10 Notification, which CALCITEK failed to do prior to publicly making
11 the above 3 labeling claims.

12 41. On or about September 19, 1989, at the request of
13 CALCITEK, a meeting was held with the FDA to discuss the FDA
14 letter, dated August 31, 1989. In short, the FDA accused CALCITEK
15 of making marketing claims that were not included in their 510(k)
16 submission (No. K840750). The FDA required CALCITEK to submit a
17 ~~new 510(k) submission including all marketing claims so that the~~
18 claims could be reviewed by the FDA. Consequently, the Integral
19 was deemed by the FDA as misbranded, adulterated and was subject
20 to seizure.

21 42. On or about September 20, 1989, CALCITEK sent a letter
22 to the FDA regarding the Integral, wherein CALCITEK requests that
23 the clinical information, submitted during the above September 19,
24 1989, meeting be accepted by the FDA as a supplement to CALCITEK's
25 510(k) submission in order to substantiate CALCITEK's marketing
26 claims.

27 43. CALCITEK was also required by the FDA to stop all
28

1 before FDA has made a final decision and that if CALCITEK had not
2 received a decision within ninety days, it would be prudent to
3 check with FDA to determine the status of the submission!

4 46. On or about September 1989, Dr. Golec determined that
5 the above 1985 blade caused Plaintiff's jaw to become infected,
6 loose and that the blade needed to be removed. Dr. Golec then
7 referred Plaintiff to DR. AIRES who confirmed Dr. Golec's
8 diagnosis. Dr. Golec and Plaintiff agreed that after the blade
9 was removed, that Dr. Golec would implant a pure titanium left
10 lower subperiosteal over the area where the bone was damaged by
11 the blade. Dr. Golec represented this device was "state-of-the-
12 art" that "everybody was doing it" and that "he would do the same
13 thing for his own family members." Plaintiff is informed,
14 believes and thereon alleges that she understood, at this time,
15 that the implants she was getting were FDA approved medical
16 devices. Plaintiff is further informed, believes and thereon
17 alleges that nobody, at any time, gave her warning regarding the
18 risks associated with this product (or any products) implanted in
19 her jaws let alone ever mention that this product (or any product)
20 implanted in her jaw was not approved by the FDA. Dr. Golec
21 offered Plaintiff a discount, which Plaintiff accepted, if she
22 allowed students to watch the procedure.

23 47. On or about October 3, 1989, Plaintiff underwent
24 emergency surgery where Dr. Golec removed the infected blade
25 implant as he said he would. On or about November 1989, Plaintiff
26 underwent two reconstructive surgeries where Dr. Golec was suppose
27 to surgically implant a pure titanium left lower subperiosteal
28

1 over the area where the bone was damaged by the blade. However,
2 Plaintiff is informed, believes, and thereon alleges that Dr.
3 Golec, without first consulting Plaintiff, also removed several
4 additional healthy teeth, and implanted a total lower
5 subperiosteal coated with Calcitite and by using Calcitite as
6 filler (such as HA grafting, HA blocks, HA particles, etc.).
7 Also, Plaintiff is informed, believes and thereon alleges that the
8 products implanted in Plaintiff's mouth were sprayed on by MR.
9 RILEY who was working for CALCITEK and Creative Custom Services, Inc. at
10 the time.

11 48. Plaintiff is informed, believes and thereon alleges that
12 CALCITEK, Dr. Golec and DR. AIRES ignored the above mentioned FDA
13 prohibition (dated April 11, 1989) and implanted the above
14 mentioned CALCITEK products into her mouth without warning her of
15 the risks associated with these products. Plaintiff was charged
16 and paid \$7,500.00 (Seven Thousand Five Hundred Dollars) for these
17 CALCITEK products.

18 49. On or about February 19, 1990, DR. AIRES informed
19 Plaintiff that she needed to have a particular right lower tooth
20 pulled and referred her once again to Dr. Golec. Plaintiff is
21 informed, believes and thereon alleges that Dr. Golec pulled the
22 designated right lower tooth but, without Plaintiff's knowledge,
23 Dr. Golec inserted a Bio-Blade along with abutments, o-rings all
24 of which were manufactured by CALCITEK, coated with Calcitite, not
25 approved by the FDA and in fact specifically prohibited to be
26 marketed when the FDA ordered, back on April 11, 1989, that
27 CALCITEK stop marketing Calcitite and Calcitite-coated products as
28

iously alleged.

50. Plaintiff is informed, believes and thereon alleges that ITEK, DR. AIRES, MR. RILEY, Creative Custom Services, inc. Dr. Maw, I, MAW, & BERGER, RALPH B. MAW D.D.S and Dr. Golec conspired and did induce Plaintiff to undergo treatment and did not fail in advance their plans to surgically implant CALCITEK products that were not approved by the FDA.

51. Plaintiff is further informed, believes and thereon alleges that the above Bio-Blade is still in Plaintiff's jawbone. Plaintiff requires ongoing medical treatment because the Bio-Blade causes ongoing infection, metallic taste, and chronic pain itching.

52. On or about March 11, 1990, DR. AIRES sold Plaintiff dental posts, at \$350 each, which included the attachments such as crowns and castable abutments and all of which were manufactured by CALCITEK and coated with Calcitite; these products were implanted/installed into Plaintiff's mouth by DR. AIRES.

53. In late March 1990, Dr. Golec recommended Plaintiff have dental implants surgically implanted in her upper jaw at \$980.00 each with a \$500.00 discount if she allowed him to use her in his practice (for a total sum of \$3,420.00); Plaintiff agreed to this offer and recommendation.

54. On or about May 30, 1990, the FDA wrote to CALCITEK regarding their 510(k) submission (No. K895680), regarding the dental implant, informing CALCITEK that the FDA cannot determine if the dental implant is "substantially equivalent" to a device marketed prior to May 28, 1976, which is the enactment date of the Medical Device

iously alleged.

50. Plaintiff is informed, believes and thereon alleges that CALCITEK, DR. AIRES, MR. RILEY, Creative Custom Services, inc. Dr. Maw, DR. MAW, & BERGER, RALPH B. MAW D.D.S and Dr. Golec conspired and did induce Plaintiff to undergo treatment and did not reveal in advance their plans to surgically implant CALCITEK products that were not approved by the FDA.

51. Plaintiff is further informed, believes and thereon alleges that the above Bio-Blade is still in Plaintiff's jawbone. Plaintiff requires ongoing medical treatment because the Bio-Blade causes ongoing infection, metallic taste, and chronic pain itching.

52. On or about March 11, 1990, DR. AIRES sold Plaintiff dental posts, at \$350 each, which included the attachments such as wings and castable abutments and all of which were manufactured by CALCITEK and coated with Calcitite; these products were implanted/installed into Plaintiff's mouth by DR. AIRES.

53. In late March 1990, Dr. Golec recommended Plaintiff have dental implants surgically implanted in her upper jaw at \$980.00 each with a \$500.00 discount if she allowed him to use her in his office (for a total sum of \$3,420.00); Plaintiff agreed to this offer and recommendation.

54. On or about May 30, 1990, the FDA wrote to CALCITEK regarding their 510(k) submission (No. K895680), regarding the dental implant, informing CALCITEK that the FDA cannot determine if the dental implant is "substantially equivalent" to a device marketed prior to May 28, 1976, which is the enactment date of the Medical Device

1 Amendments, and requested further information to enable the FDA to
2 make the determination. Significantly, the FDA, in this letter,
3 told CALCITEK that it considered CALCITEK's labeling claims
4 regarding the Integral to be unsupported until CALCITEK could
5 submit adequate original data based on animal studies to support
6 its claims.

7 55. Specifically, in the above mentioned FDA letter, dated
8 May 30, 1990, the FDA informed CALCITEK that their claim that bone
9 and Calcitite coating actually bond is unsupported. The FDA
10 further determined the bond between it and bone did not have
11 intervening fibrous tissue, no chemical bonding was demonstrated,
12 let alone bonding on a regular basis. The FDA determined that the
13 bone directly oppose the HA coating without intervening fibrous
14 tissue.

15 56. Significantly, on information and belief Plaintiff
16 alleges, that in the FDA letter dated May 30, 1990, the FDA
17 informed CALCITEK not to market its product called the Integral
18 and that if it did so it would be violating 21 CFR 807.87(f) and
19 (h) of the Federal Food Drug and Cosmetic Act. Plaintiff is
20 further informed, believes and alleges that CALCITEK did violate
21 Section 807.87(f) by marketing the Integral without FDA approval.

22 57. After the FDA informed CALCITEK that the Integral was
23 not "substantially equivalent" and not to be marketed, Plaintiff
24 underwent two operations where Dr. Golec surgically implanted four
25 Integrals into Plaintiff's upper jawbone; one of the operations
26 was performed in June of 1990 and the other was performed in July
27 of 1990. Plaintiff paid \$4,000.00 (Four Thousand Dollars) for the
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1 Integrals. Dr. Golec told Plaintiff the Integrals were "state-of-
2 the art."

3 58. Plaintiff is informed, believes and thereon alleges that
4 CALCITEK, DR. AIRES, MR. RILEY, , Dr. Maw,
5 CUTRI, MAW, & BERGER, RALPH B. MAW D.D.S and Dr. Golec conspired
6 together to sell Plaintiff the above mentioned four Integrals
7 violating 21 CFR 807.87(f) and (h) of the Federal Food Drug &
8 Cosmetic Act and to further violating the Act by implanting the
9 Integrals into her jaw. Plaintiff was not warned that the
10 Integral was deemed by the FDA as not to be "substantially
11 equivalent," and not approved for marketing, nor was she informed
12 of any of the other risks associated with the Integral.

13 59. On or about June 21, 1990, DR. AIRES had Dr. Golec
14 surgically implant three of the Integrals (along with their
15 corresponding abutments and o-rings) into Plaintiff upper jaw.
16 Again on or about July 1990, DR. AIRES sent Plaintiff back to Dr.
17 ~~Golec for the fourth Integral (along with abutments and o-rings),~~
18 which Dr. Golec surgically implanted also into her upper jaw.

19 60. Plaintiff is informed, believes and thereon alleges that
20 the above mentioned Integrals (and corresponding abutments and o-
21 rings) were all manufactured by CALCITEK and all coated with
22 Calcitite and anchored into Calcitite blocks (in lieu of natural
23 bone) that were previously implanted by Dr. Golec back in October
24 and November of 1989. On information and belief, Plaintiff
25 alleges that she was not told, at the time, that the above
26 products were coated with Calcitite. Plaintiff is further
27 informed, believes and thereon alleges that Dr. Golec, DR. AIRES,
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1 MR. RILEY, CREATIVE CUSTOM DESIGN, Dr. Maw, CUTRI, MAW, & BERGER,
2 RALPH B. MAW D.D.S and CALCITEK conspired together to surgically
3 implant the Integral (and corresponding abutments and o-rings)
4 into Plaintiff's jaws. Plaintiff is further informed, believes
5 and thereon alleges that she was not adequately informed about the
6 risks of the products and nor of the surgical procedure used.
7 Plaintiff further is informed, believes and thereon alleges that
8 the use of CALCITEK products caused extensive damage to
9 Plaintiff's jaws that later required three biopsies, and three
10 emergency surgeries.

11 61. Once again, in another warning letter dated December 3,
12 1990, the FDA informed CALCITEK the Integral is not "substantially
13 equivalent" to devices marketed in interstate commerce prior to
14 May 28, 1976 (the enactment date of the Medical Device Amendments)
15 or to any device which has been reclassified into class I (General
16 Controls) or class II (Performance Standards). The decision by
17 ~~the FDA was based on the fact that the Integral has a new intended~~
18 use. The labeling claims outlined below were not permitted by the
19 FDA to be used: (a) "The coating permits bone to actually bond
20 with implant surface." (b) "Bone-bonding characteristics of
21 hydroxylapatite material." (c) "Biochemical tests on bone loaded
22 and unloaded implants dramatically reveal the superiority of
23 Calcitite-coated implants on both degree and rate of fixation in
24 bone." (d) "Additionally, the presence of more supporting bone on
25 the Calcitite-coated implant surfaces (versus uncoated implants)
26 may contribute to continued implant success." (e) "But with
27 Calcitite-coated implants, bone grows more rapidly on, and covers
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1 a greater percentage of the implant surface. Plus, there are
2 virtually no fibrous tissue elements between the bone and the
3 implant." (f) "Most important of all, this bonds strongly to the
4 Calcitite-coating. This bone-bonding phenomenon mirrors the bone-
5 bonding associated with dense hydroxylapatite." (g) "Histological
6 studies demonstrate why Calcitite-coated implants may perform
7 better than uncoated implants." (h) "...Calcitite-coated
8 implants, ... covers a greater percentage of the implant surface.
9 Plus there are virtually no fibrous tissue elements between the
10 bone and the implant." On information and belief, Plaintiff
11 alleges that all of the above claims (a) -- (h) were made to the
12 public.

13 62. Plaintiff is informed, believes and thereon alleges
14 that, in the above December 3, 1990 letter, the FDA informed
15 CALCITEK it classified the Integral into Class III (Premarket
16 Approval), under Section 513(f) of the Federal Food, Drug, and
17 ~~Cosmetic Act (Act). The FDA further informed CALCITEK that Class~~
18 III classification, pursuant to Section 515(a)(2) of the Act
19 requires the Integral to have an approved premarket approval
20 application (PMA) before it can be legally marketed, unless the
21 device is reclassified. The FDA further stated that any
22 commercial distribution of this device prior to approval of a PMA,
23 or the effective date of any order by the FDA reclassifying this
24 device into class I or II, would be a violation of the Act.
25 Clinical investigations of this device must be conducted in
26 accordance with the investigational device exemptions (IDE)
27 regulations.

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1 63. Plaintiff is informed, believes and thereon alleges that
2 CALCITEK commercially distributed the Integrals prior to approval
3 of a PMA.

4 64. On or about November 1991, DR. AIRES was treating
5 Plaintiff for a lesion adjacent to an Integral and he referred her
6 back to Dr. Golec, who informed Plaintiff that he had implanted
7 Calcitite-coated dental implants including Calcitite Particles,
8 which Plaintiff was required and did pay \$600.00 for the Calcitite
9 particles. Plaintiff demanded to know more about Calcitite and
10 Dr. Golec gave her a 5 page information article on Calcitite-
11 coated implants entitled "Biointegration Integral; The natural
12 step forward in dental implants written on or about 1987 by
13 CALCITEK. Plaintiff is informed, believes and thereon alleges
14 that this article contains most, if not all, of the claims the FDA
15 told CALCITEK not to make as set forth above.

16 65. On information and belief, Plaintiff alleges that, from
17 ~~October 1991 through November 1991, the FDA conducted an onsite~~
18 inspection of CALCITEK at its location in Carlsbad, California.
19 The purpose of the inspection was to collect Initial Recall
20 Information and to perform a full statutory GMP inspection. The
21 inspection revealed numerous major GMP and sterilization
22 deficiencies such as follows: (1) no ETO sterilization
23 specifications in the DMR, (2) no documentation or information
24 known about ETO cycle parameters or bioburden testing or controls,
25 (3) no ETO resterilization guidelines; no revalidation or their
26 radiation sterilization procedures, (4) six non-reported MDR
27 reportable complaints for injury, (5) no periodic audits of
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1 contract sterilizers, (6) inadequate audit procedures for contract
2 sterilizers, (7) non-validation of new software revisions, (8) not
3 all procedures for sterilization are being followed by their
4 contract Sterilizers, (9) clean room air pressure is not being
5 monitored, (10) there are no Critical component supplier
6 agreements, (11) percentage of critical components not maintained,
7 (12) incomplete maintenance records for the ionizing air gun
8 filter, (13) and interim specification change procedures are not
9 in writing.

10 66. Plaintiff is informed, believes and thereon alleges that
11 during the above mentioned inspection the FDA noted the following
12 GMP deficiencies with respect to the Integral: (1) no testing of
13 Argon, or Hydrogen gases used in the application of HA surface
14 coating, (2) humidity not monitored during HA processing machine,
15 (3) observed an apparent uncleaned HA processing machine, (4) non-
16 adherence to written DMR procedures and employee error caused a
17 ~~labeling mixup resulting in a device recall,~~ (5) ~~HA particles and~~
18 HA coated implants lack testing to determine the content of the HA
19 following irradiation sterilization, (6) numerous (13) MDR
20 reported events for malfunction were not reported within the 15
21 day reporting timeframe.

22 67. On or about March 1992, Dr. Golec died. On or about
23 April 20, 1992, DR. AIRES wrote a note to Plaintiff assuring her
24 that the implant they implanted in her mouth was called an
25 "Integral" manufactured by CALCITEK and he assured Plaintiff that
26 it was an FDA approved device. Plaintiff is informed, believes
27 and thereon alleges that the subject Integrals were not FDA
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1 approved as the above FDA letters prove.

2 68. On information and belief, Plaintiff alleges that, on or
3 about April 27, 1992, Dr. Maw, CUTRI, MAW, & BERGER, RALPH B. MAW
4 D.D.S's office wrote a note to Plaintiff reminding her that she
5 has CALCITEK Integrals in her upper jaw and a subperiosteal
6 implant in her lower jaw and that these devices were FDA approved.
7 Plaintiff is informed, believes and thereon alleges that the
8 above note from Dr. Maw, CUTRI, MAW, & BERGER, RALPH B. MAW
9 D.D.S's office note contains a false statement in that the devices
10 implanted in Plaintiff's jaw were not FDA approved.

11 69. Plaintiff is informed, believes and thereon alleges
12 that, on or about May 15, 1992, the FDA sent a warning letter to
13 CALCITEK (regarding the above inspection of their medical device
14 facility in Carlsbad, California between 10/8/91--11/1/91) wherein
15 they inform CALCITEK that they documented numerous violations
16 associated with Calcitite and Calcitite-coated products. The FDA
17 said that the products, "Biointegrated Dental Implant Systems" and
18 "Calcitite Nonresorbable Hydroxylapatite Bone Grafting Material,"
19 are devices as defined by § 201(h) of the Federal Food, Drug, and
20 Cosmetic Act. The violations included deviations from the Good
21 Manufacturing Practice for Medical Devices (GMP) regulation, Title
22 21, Code of Federal Regulations (CFR), Part 820, which cause
23 CALCITEK's hydroxylapatite (HA) containing products to be
24 adulterated within the meaning of § 501(h) of the Act, including the
25 following: (1) Failure to test each lot of finished device for
26 conformance with device specifications prior o release for
27 distribution, as required by 21 CFR 820.160. For example, the
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1 hydroxylapatite content or crystallinity is not properly
2 characterized in the coating of each lot of hydroxylapatite coated
3 devices or packaged hydroxylapatite particles, and the pass/fail
4 criteria for the coating allow whitlockites and hydroxylapatite
5 without regard to their relative ratios. In addition, the
6 11/26/91 study entitled "The Effects of Gamma Sterilization on HA
7 Particles and HA Coatings" is not sufficient to justify the
8 absence of tests conducted on devices or test strips following
9 gamma irradiation prior to release of finished devices for
10 distribution. (2) Failure to assure that all quality assurance
11 checks are adequate and appropriate for their purpose and are
12 performed correctly, as required by 21 CFR 820.20(a)(4). For
13 example, the hydroxylapatite content or crystallinity is not
14 properly characterized in the coating of each lot of
15 hydroxylapatite coated devices or packaged hydroxylapatite
16 particles and the pass/fail criteria for the coating allow
17 whitlockites and hydroxylapatite without regard to their relative
18 ratios and neither devices nor test strips are tested following
19 gamma irradiation prior to release for distribution. (3) Failure
20 to control environmental conditions at the manufacturing site to
21 prevent contamination of the device, where environmental
22 conditions could have an adverse effect on the device's fitness
23 for use, as required by 21 CFR 820.46. For example, humidity is
24 not monitored during the hydroxylapatite coating operation in the
25 plasma spray coating room. (4) Failure to examine device
26 labeling materials for identity, as required by 21 CFR 820.120(d).
27 For example, the container package label for catalogue N. 0803,
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1 lot 910589, a 13 mm Integral 4.0 Implant was labeled with a
2 container package label that erroneously stated it was an 8 mm
3 implant. (5) Failure to establish procedures for specification
4 control measures to assure that the design basis for the device is
5 correctly translated into approved specification, as required by
6 21 CFR 820.100(a)(1). For example, the effect of humidity could
7 not have been part of the validation of the HA coating operation
8 in the plasma spray coating room. (6) Failure of the device
9 master record to include production environment specification, as
10 required by 21 CFR 820.181(d). There is no specification for
11 humidity in the plasma spray coating room. (7) Failure to
12 dispose of by-products and chemical effluents in a timely, safe,
13 and sanitary manner, as required by 21 CFR 820.56(d). For
14 example, there as a pink-colored material deposited along the
15 seams of a metal plate on the HA processing machine on 10/10/91.
16 (8) Failure to maintain a device history record to demonstrate
17 that the device is manufactured in accordance with the device
18 master record, as required by 21 CFR 820.184. For example, the
19 SWEEO ROOM cleaning record did not clearly indicate whether the
20 processor was cleaned or whether production was still continuing
21 from the previous day.

22 70. On information and belief, Plaintiff alleges that during
23 the inspection, FDA investigator collected labeling for "Calcitite
24 Nonresorbable Hydroxylapatite Bone Grafting Material," which
25 revealed that these devices are misbranded within the meaning of
26 §§ 502(a) and 502(o) of the Act. The labeling for the devices is
27 false or misleading within the meaning of § 502(a) in that
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1 statements such as: (1) "Since Calcitite HA is similar to mineral
2 naturally found in your body, it is completely compatible with
3 your body"; (2) "Since Calcitite is a mineral naturally found in
4 your body, it is completely compatible with your body"; and (3)
5 "....eliciting no inflammatory or foreign body response."
6 According to the FDA, these three statements represent or suggest
7 that the material is completely biocompatible, which
8 representations or suggestions are false or misleading or
9 otherwise contrary to fact because CALCITEK grafts are non-
10 autogenous grafts and cannot be completely compatible.

11 71. On information and belief, Plaintiff alleges that
12 according to the FDA, in their May 15, 1992 warning letter, the
13 "Calcitite Nonresorbable Hydroxylapatite Bone Grafting Material"
14 is misbranded within the meaning of Section 502(o) of the Act, in
15 that a premarket notification submission was not provided as
16 required by Section 510(k) and 21 CFR 807.81(a)(3), and was not
17 found to be "substantially equivalent" as required by Section
18 513(i)(1)(A), when significant changes or modifications were made
19 to the device. For example, the statement: "...can retard further
20 progression of gum disease...aiding in preventing its recurrence"
21 constitutes a major change or modification in the intended use of
22 the device Calcitite 2040 Bone Graft Material, described in
23 K852682, and requires a premarket notification submission.

24 72. Plaintiff is informed, believes and thereon alleges that
25 during the above inspection, FDA investigators also collected
26 labelling and promotional material for the "Biointegrated Dental
27 Implant Systems," which revealed that these devices are
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1 adulterated within the meaning of Section 501(f)(1)(B) of the Act,
2 in that the devices have been classified in Class III under
3 Section 513(f) of the Act and are required to have in effect an
4 approved application for premarket approval, and no approvals have
5 been granted. In a letter dated December 3, 1990, regarding
6 K895680, a premarket notification submitted for the Integral
7 device, the "Biointegrated Dental Implant System" was classified
8 in Class III when it is labeled with claims, including: (1) "The
9 coating permits bone to actually bond with implant surface." (2)
10 Bone-bonding characteristics of hydroxylapatite material." and (3)
11 Biochemical tests on both loaded and unloaded implants
12 dramatically reveal the superiority of Calcitite-coated implants
13 on both degree and rate of fixation in bone." Moreover,
14 statements such as: (1) "...to ensure complete bony fixation....,"
15 (2) "Biointegration and implant stability are enhanced by the
16 Calcitite brand of dense hydroxylapatite (HA) coating..." and (3)
17 "...to ensure a stable biocompatible interface with bone..." ----
18 - found in labeling and promotional materials for the Integral and
19 Integral Omniloc Biointegrated Dental Implant Systems cause these
20 devices to be unapproved Class III devices.

21 73. Plaintiff is informed, believes and thereon alleges that
22 during the above inspection, FDA investigators also determined
23 that the "Biointegrated Dental Implant Systems are also misbranded
24 within the meaning of Section 502(t)(2) of the Act in that
25 information was not submitted within the reporting time frames to
26 the FDA as required by 21 CFR Part 803, the Medical Device
27 Reporting (MDR) regulation. Specifically, CALCITEK failed to
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1 submit a telephone report within 5 calendar days and a written
2 report within 15 working days of CALCITEK's initial receipt of
3 information which reasonably suggested that one of its
4 commercially distributed devices caused or contributed to a
5 serious injury. CALCITEK's retrospective submission in October
6 1991 of 21 events identified them as malfunctions, however, FDA
7 considers these events to represent serious injuries as defined in
8 the MDR regulation under 21 CFR Part 803.3(h). 74. On
9 information and belief, Plaintiff alleges that also according to
10 the above FDA warning letter, the FDA further determined that the
11 loss of or failure of osseointegrate of an endosseous implant
12 device leaves the patient with a compromised intra-oral structure
13 (i.e., supporting bony tissue damage) which may allow entry of
14 oral fluid and microorganisms into the implant site, infection,
15 and implant mobility; and necessitates medical intervention by a
16 health-care professional to remove the implant, promote healing,
17 and prevent further bone loss, thereby precluding permanent tissue
18 damage. The failure to osseointegrate or fracture of the implant
19 may also impair the patients's masticatory function, necessitating
20 medical intervention to remove and revise the implant, to preclude
21 permanent impairment of a body function. Since the failure to
22 osseointegrate will not correct itself, it cannot be viewed as
23 temporary impairment, but must be viewed as permanent impairment.
24 When a firm receives a report that states that there was a
25 failure of the device to osseointegrate and medical intervention
26 was needed, lacking any other information, the incident is
27 reportable as a serious injury that required medical intervention

1 to prevent permanent impairment of a body function or structure.

2 75. Plaintiff is informed, believes and thereon alleges that
3 CALCITEK was also found by the FDA to be in error in the
4 definitions used to identify reportable malfunctions. Perforation
5 of the sinus cavity is considered a serious injury as well as a
6 recognized complication. Exfoliation or removal of an implant
7 (before or after restoration) and fracturing of the bone are
8 serious injuries which require medical or surgical intervention to
9 preclude permanent impairment of the body structure or function.
10 Fracturing of the blade portion of the drill and mobility of the
11 implant or complete augmentation would also be considered serious
12 injuries unless CALCITEK obtains information and/or a statement
13 from the health-care professional with 5 calendar days that no
14 medical or surgical intervention was required to remove the
15 fractured blade or correct the reported mobility problem. FDA
16 also considers outright fractures of the implant to be serious
17 injuries, especially those where the fracture occurs in the bone
18 or soft tissue area, and CALCITEK's definitions should be revised
19 accordingly.

20 76. Beginning on or about August 1991, Plaintiff started
21 having lesions in her mouth. From about August 1991 through
22 approximately November 1992, Plaintiff employed DR. AIRES to
23 diagnose and treat and rehabilitate her dental condition. DR.
24 AIRES treated Plaintiff's jaw infections with antibiotics as puss
25 was oozing from her gums.

26 77. After Dr. Golec died, Plaintiff was referred by Dr.
27 Francis Howell (a dentist that treated Plaintiff years earlier) to
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1 DR. EVASIC for treatment since DR. EVASIC held himself out as a
2 specialist in dental implantology. In 1992, Plaintiff employed
3 DR. EVASIC and DOES 1-10 to diagnose and treat and rehabilitate
4 her dental condition. Pursuant to this employment, Defendants
5 rendered professional services in the diagnosis, treatment, and
6 care of Plaintiff for her condition. Plaintiff remained under the
7 care of these Defendants up to and including August 1995.

8 78. Plaintiff is informed, believes and thereon alleges that
9 DR. EVASIC held himself out and claimed to be a specialist in
10 dental implantology, a member of the "American Academy of Implant
11 Dentistry" (AAID) and worked with or affiliated with the
12 internationally acclaimed Scripps health care facilities located
13 in La Jolla known as the Scripps Research Institute, the Scripps
14 Clinic and Research Foundation, or the Scripps Institutions of
15 Medicine and Science; these representations were false.

16 79. On information and belief, Plaintiff alleges that DR.
17 EVASIC also misrepresented to Plaintiff that he was the Director
18 of "SCRIPPS IMPLANT DENTISTRY EDUCATION & RESEARCH CENTER", that
19 he also worked through the Scripps Center For Dental Care at the
20 Scripps Torrey Pine Campus and associated with AAID, which turns
21 out not to be recognized in the State of California and not a
22 legal specialty. Some of these misrepresentations can be found in
23 the Yellow Pages, in the Magazine Dentistry Today (March 1990),
24 and on his letterhead.

25 80. On or about November 1992, DR. EVASIC removed one of the
26 Integrals from the upper jaw of Plaintiff and treated her with
27 antibiotics through August 1995, during which time puss was oozing
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1 from the sides of the remaining Integrals.

2 81. On or about February 3, 1993, the FDA informed CALCITEK
3 that they completed a review of the labeling and Current Good
4 Manufacturing issues (CBMPs) involved in the Warning Letter WL-51-
5 2, dated May 15, 1992, and CALCITEK's response. The FDA
6 encouraged CALCITEK to comply with the ASTM standard and lower the
7 allowable maximum trace concentration in the hydroxylapatite
8 powder from 550 ppm to 50 ppm or otherwise the FDA could consider
9 CALCITEK's failure to comply with current good manufacturing
10 practices in the industry.

11 82. In June 1995 and multiple times since then, CALCITEK
12 represented that all of the products in Plaintiff's mouth were
13 grandfathered in from an earlier 510(k) submission to the FDA.
14 Plaintiff did not and could not obtain evidence that showed
15 CALCITEK's representations were false until late May 1999 as set
16 forth herein.

17 83. On or about August 21, 1995, Bruce Johnson, D.M.D. got
18 involved with Plaintiff on an emergency basis with regard to
19 chronic periimplant infections. The affected implants were in the
20 maxillary arch in approximate positions 8, 9, and 10. Dr. Johnson
21 removed the implant in position 8, CALCITEK HA grafting (i.e.,
22 Calcitite), abutments and o-rings (coated with Calcitite) due to
23 periimplant infection and bone loss.

24 84. In February, 1996, Plaintiff learned for the first time
25 that the 1990 Bio-Blade was implanted in her jawbone.

26 85. On August 22, 1996, CALCITEK through MR. RILEY declared
27 the following, amongst other things, under penalty of perjury: (1)
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1 that MR. RILEY is the Director of Technical Services for CALCITEK,
2 (2) that he had been involved with CALCITEK's line of dental
3 implants since their inception, (3) that Calcitite was originally
4 cleared to market by the FDA in the early 1980s, (4) that HA
5 particles (i.e., referred herein as "Calcitite particles") sold by
6 CALCITEK were cleared to market by the FDA by the process of
7 510(k), (5) that a submission was made to the FDA claiming
8 equivalency to a predicate device (the predicate device to which
9 Calcitite was compared was freeze-dried bone.), (6) that each
10 subsequent reconfiguration and additional product containing
11 hydroxylapatite has been cleared to market by the FDA prior to its
12 sale to the public, (7) CALCITEK's blade implants have never been
13 subject to a recall of any nature, and (8) the Integral is FDA
14 approved since he stated that all of the CALCITEK products were
15 approved by the FDA before being sold to the public.

16 86. Plaintiff is informed, believes and thereon alleges that
17 the above comments made by CALCITEK through MR. RILEY are material
18 misrepresentations that go to the very heart of the parties
19 controversy as alleged herein in detail.

20 87. On or about September 24, 1996, Plaintiff underwent
21 emergency reconstructive surgery, where Dr. Johnson removed two
22 Integrals (implants No. 9 & 10, with corresponding HA grafting
23 (i.e., Calcitite), abutments and o-rings) were cut out of
24 Plaintiff's jaw due to periimplant infections and bone loss. On
25 information and belief, Plaintiff alleges that a Catscan
26 radiograph of Plaintiff's jaw shows significant maxillary alveolar
27 bone loss which will require significant bone grafting as
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1 preparation for new dental implants.

2 88. On information and belief, Plaintiff alleges that on or
3 about July 10, 1998, CALCITEK (through Richard LaRiviere, a Vice
4 President and Director) declared, under penalty of perjury, that
5 CALCITEK never sought PMA approval on any CALCITEK product (i.e.,
6 never sought premarket approval on any medical device), that the
7 Integral did not receive premarket approval from the FDA and that
8 the Integral was seized from the market.

9 89. On or about May 1999, Plaintiff learned for the first
10 time, from an Orange County case entitled Bentele v. CALCITEK,
11 Case No. 747549, that Defendants had been misrepresenting that the
12 CALCITEK devices implanted in Plaintiff's mouth were FDA approved
13 when they were and are definitely not FDA approved. It took
14 Plaintiff an extensive period of time to read through the court
15 file consisting of four volumes and to assimilate the highly
16 technical documents and come to the conclusion that Defendants
17 have been misrepresenting the facts herein alleged.

18 90. Plaintiff is informed, believes and thereon alleges the
19 court in Bentele ruled in October, 1998, that there was enough
20 evidence to support the false advertising claim to substantiate
21 exemplary damages.

22 91. Plaintiff is informed, believes and thereon alleges that
23 at all times mentioned herein, CALCITEK, Dr. Golec, DR. AIRES, MR.
24 RILEY, Dr. Maw, CUTRI, MAW, & BERGER,
25 RALPH B. MAW D.D.S conspired to use Plaintiff as a test subject
26 and failed to inform her that the products implanted in her mouth
27 were not FDA approved.

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1 biologically bonds to natural bone; (2) deposition of new bone
2 occurs not just at the old bone site, but also on the HA coating
3 causing a significant increase in the rate at which the surgical
4 site heals, (3) Integral implants are provided sterile and are
5 protected by a special double wrapped holding-vial transfer system
6 for easy delivery to a sterile field, (4) the design of the
7 Integral implant bodies with the Calcitite coating create rapid
8 initial stabilization of the implant.

9 95. During all times mentioned herein, Plaintiff understood
10 that she was being treated by doctors in private practice that
11 were not conducting any studies or training courses and had no
12 affiliations or other ties to CALCITEK. Defendants and each of
13 them failed to disclose they were affiliated with CALCITEK and
14 concealed the fact that they were using Plaintiff in their
15 clinical trials to test CALCITEK's products.

16 96. On information and belief Plaintiff alleges that all of
17 the products implanted in her mouth were manufactured by CALCITEK
18 and coated with CALCITEK's version of HA.

19 97. Plaintiff is informed, believes, and thereon alleges
20 that for all times mentioned in this complaint, it has been
21 extremely difficult to discover the extent of her injuries in
22 light of the misrepresentations and concealment of procedures and
23 implantation of medical devices by the dentists working with or
24 for CALCITEK as herein alleged. Furthermore, on information and
25 belief Plaintiff alleges, that coupled the concealment and
26 misrepresentations alleged herein, Plaintiff cannot simply take an
27 x-ray of her mouth to see what was implanted and the condition of
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1 her own bone and teeth since HA appears as bone does on an x-ray
2 and it is hard for experts to distinguish the two without
3 intrusive and expensive surgical procedures.

4 98. On information and belief, Plaintiff alleges that it was
5 not until on or about August 10, 1998, that Plaintiff first
6 learned (from the Orange County case entitled Bentele v. CALCITEK,
7 Case No. 747549) of the facts herein alleged regarding the
8 communications between CALCITEK and the FDA. Plaintiff is further
9 informed, believes and herein alleges that she was continuously
10 lied to by the defendants and that there had been a concerted
11 effort to conceal these the facts regarding FDA approval, false
12 advertising, and all of the misrepresentations herein alleged.

13 99. On information and belief, Plaintiff alleges that
14 Calcitite is carcinogenic but CALCITEK has and continues to deny
15 that Calcitite is carcinogenic.

16 100. Plaintiff believes and thereon alleges that each and
17 every act and all conduct described herein, that was committed
18 alleged to be committed by Defendants herein was also committed by
19 an appropriate officer, director, manager, supervisor or managing
20 agent of the Defendants under conditions known to create a
21 probability of serious injury. In short, each Defendant herein
22 ratified the actions or omissions.

23 101. On information and belief, Plaintiff alleges that the
24 Integrals caused Plaintiff to sustain permanent injuries that
25 still require extensive bone grafting to correct the problem with
26 a cost of \$45,000.00 (Forty-Five Thousand Dollars) for the
27 surgeon's fee not to mention facility fees, anesthesiology fees,
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1 x-ray fees, post-operative fees and medication fees.

2 102. As a further direct and proximate result of the acts and
3 omissions herein, Plaintiff has continuously sustained personal
4 injuries since 1985, and as a direct and proximate result of the
5 acts and omissions herein, Plaintiff has and will sustain and
6 suffer the following: (1) permanent loss of teeth and jawbone
7 material, (2) facial deformity, (3) the inability to chew and eat
8 most foods, (4) difficulty in digesting food, (5) chronic metallic
9 taste in her mouth, (6) past and future chronic pain, (5) past
10 and future pain and suffering from mental anguish, (7) past and
11 future loss of sleep, (8) past and future impairment of the
12 ability to enjoy life, (9) past and future medical expenses, (10)
13 past and future lost wages, and (11) temporary and permanent
14 disabilities. The exact amount of the above damages are unknown
15 at this time.

16 I

17 ~~FIRST CAUSE OF ACTION~~

18 (NEGLIGENCE PER SE --- Violation of FDA Regulations)

19 103. Plaintiff incorporates paragraphs 1-102 and their
20 respective facts and allegations into this cause of action.

21 104. This cause of action is against all Defendants.

22 105. Plaintiff is informed, believes and thereon alleges that
23 Defendants failed to exercise ordinary care in complying with
24 applicable federal regulations governing the following: designing,
25 manufacturing, labeling, testing, inspecting, distributing,
26 providing, marketing, warranting, packaging, selling, recalling of
27 the medical devices, and warning the public of the hazards of the
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1 medical devices.

2 106. When a medical device is not "substantially equivalent"
3 it is a Class III device and has to receive premarket approval
4 (PMA) from the federal Food and Drug Administration (FDA) before
5 it could be marketed commercially. (See 21 C.F.R. §886.4275
6 (1996); 21 C.F.R. §§360c(a)(1)(C), 360e; see also *Medtronic, Inc.*
7 *v. Lohr*, (1996) 518 U.S. 470)

8 107. As a preliminary step in the approval process, qualified
9 manufacturers may obtain an investigational device exemption under
10 the Medical Device Amendments of 1976 (MDA or the Act), which
11 permits it to investigate the safety and effectiveness of the
12 device by conducting clinical trials on humans. (See 21 U.S.C.
13 §§360e(a), 360j(g))

14 108. The PMA process requires a manufacturer to submit a
15 detailed application to the FDA, including information pertaining
16 to product specifications, intended use, manufacturing methods,
17 and proposed labeling. The FDA refers each application to a panel
18 of qualified experts who prepare a report and recommendation
19 accepting or rejecting the application. Once the product receives
20 PMA, the sponsor of the product may begin to market the product.
21 Any subsequent changes in the product require submission of a PMA
22 supplement application. Furthermore, to ensure continued validity
23 of the PMA, the product sponsor is required to submit postapproval
24 reports at one-year intervals, identifying any changes in the
25 device or any reports from clinical investigation or scientific
26 literature concerning the device.

27 109. Not all, or even most, Class III devices on the market
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1 today have received premarket approval because of two important
2 exceptions to the PMA requirement. First, Congress realized that
3 existing medical devices could not be withdrawn from the market
4 while the FDA completed its PMA analysis for those devices. The
5 statute therefore includes a "grandfathering" provision which
6 allows pre-1976 devices to remain on the market without FDA
7 approval until such time as the FDA initiates and completes the
8 requisite PMA.

9 110. Second, to prevent manufacturers of grandfathered
10 devices from monopolizing the market while new devices clear the
11 PMA hurdle, and to ensure that improvements to existing devices
12 can be rapidly introduced into the market, the Act also permits
13 devices that are "substantially equivalent" to pre-existing
14 devices to avoid the PMA process.

15 111. Although "substantially equivalent" Class III devices
16 may be marketed without the rigorous PMA review, such new devices,
17 ~~as well as all new Class I and Class II devices, are subject to~~
18 the requirements of §360(k). That section imposes a limited form
19 of review on every manufacturer intending to market a new device
20 by requiring it to submit a "premarket notification" to the FDA
21 (the process is also known as a §510(k) notification that the
22 device is "substantially equivalent" to a pre-existing device, it
23 can be marketed without further regulating analysis (at least
24 until the FDA initiates the PMA process for the underlying pre-
25 1976 device to which the new device is "substantially
26 equivalent"). The §510(k) review is completed in an average of
27 only 20 hours.

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1 112. Notwithstanding, FDA requirements include labeling
2 regulations which require manufacturers to every medical device to
3 include with the device a label containing "information for use,
4 ... and any relevant hazards, contraindications, side effects, and
5 precaution." (21 CFR §§801.109(b) and (c) (1995)). Similarly,
6 manufacturers are required to comply with "Good Manufacturing
7 Practices," (GMP's) which are set forth in the Code of Federal
8 Regulations. GMP regulations impose comprehensive requirements
9 relating to every aspect of the device-manufacturing process. (See
10 21 CFR §§820.20 - 820.198 (1995))

11 113. Plaintiff is informed, believes, and thereon alleges,
12 that Defendants, in doing the foregoing acts/omissions, failed to
13 exercise due care under the circumstances toward Plaintiff, and
14 knew or should have known that the same was capable of causing and
15 did cause personal injuries to the Plaintiff.

16 WHEREFORE, Plaintiff demands judgment as set forth below.

17- JF

18 SECOND CAUSE OF ACTION

19 (FRAUD -- Concealment, Misrepresentation, False Advertising)

20 114. Plaintiff incorporates paragraphs 1-102 and their
21 respective facts and allegations into this cause of action.

22 115. This cause of action is against all Defendants

23 116. This cause of action is for fraudulent concealment,
24 knowing/intentional misrepresentation, and false advertising.

25 117. Plaintiff is informed, believes and thereon alleges the
26 Section 510(k) submissions by CALCITEK, as herein alleged, were
27 never considered "approved" by the FDA and this is easily verified

1 by examining the letter from the April 11, 1989 letter from the
2 FDA where CALCITEK was told to stop marketing it's products as
3 mentioned herein until they completed the lengthy PMA process and
4 informing CALCITEK that it had been marketing the medical devices
5 in violation of the Federal Food Drug and Cosmetic Act.

6 118. On information and belief, Plaintiff alleges that
7 CALCITEK represented to the FDA and to the public, both prior to
8 and following Plaintiff's injuries and the injury of other
9 patients/consumers, that the subject medical devices were safe,
10 fit, free of defects, and met federal standards.

11 119. Plaintiff is further informed, believes and thereon
12 alleges that during all times mentioned and prior to any injuries
13 as alleged herein, CALCITEK had actual knowledge of the claimed
14 defects with their products, falsely and fraudulently continued to
15 make representations that they were safe, fit, free of defects and
16 met federal standards; all for the purpose of inducing persons to
17 ~~purchase and implant the medical devices and in order to avoid~~
18 claims for damages for injury or death resulting from the defects.

19 Plaintiff is further informed, believes and thereon alleges that
20 CALCITEK gave no warning of the deficiencies to users and the
21 defects are not discoverable without elaborate or extensive tests.

22 120. On information and belief, Plaintiff alleges that, all
23 of the published misrepresentations alleged herein were made to
24 the general public, which includes Plaintiff.

25 121. Plaintiff is informed, believes and thereon alleges,
26 that Defendants had actual knowledge, as a result of tests they
27 had performed and as the result of reported injuries that the
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1 subject medical devices were unsafe and unreasonably dangerous for
2 the use intended. Plaintiff is further informed, believes and
3 thereon alleges that despite such knowledge CALCITEK intentionally
4 and falsely failed to warn users to the dangers of Calcitite and
5 Calcitite-coated products such as the Integral, blades, castable
6 abutments and o-rings, grafting, blocks, particles and granulars
7 and the public generally of the danger and risk of using such
8 medical devices. Plaintiff relied on such false representations
9 and was unable to obtain information concerning the true facts and
10 obtain sufficient information from the FDA until approximately May
11 1999. Consequently, Defendants failure to disclose all known and
12 material facts was misleading and hindered the Plaintiff from
13 bringing an action. The concealment of facts alleged herein
14 tolled any statute of limitations for the causes of action set
15 forth in this First Amended Complaint.

16 122. In doing the things herein alleged, Defendants
17 ~~intentionally concealed or suppressed the material facts mentioned~~
18 herein with the intent to defraud the Plaintiff. Some of the
19 material facts concealed or suppressed are as follows: (1) the
20 medical devices in Plaintiff's mouth are not "substantially
21 equivalent" to devices marketed prior to May 28, 1976, and/or not
22 FDA approved, (2) the devices implanted in Plaintiff's mouth are
23 not fit for their intended use and do not meet minimum GMP
24 standards; (3) Defendant dentists are not "specialists" in
25 implantology, (4) that Defendants implanted CALCITEK products in
26 Plaintiff's mouth and that they were covered with Calcitite, (5)
27 that Defendant dentists, Defendant dental corporations and Dr.

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1 Golec were shareholders of CALCITEK and/or worked as research
2 clinicians for CALCITEK and/or were CALCITEK's alter ego, and (6)
3 that MR. RILEY was a Director and employee of CALCITEK while at
4 the same time actively involved with creative Custom Services, inc. as
5 herein alleged. ----- The suppression or concealment of the
6 above material facts were kept from Plaintiff in order to defraud
7 her.

8 123. Plaintiff is informed, believes and thereon alleges
9 that, at all times mentioned herein, CALCITEK also advertised that
10 Calcitite and Calcitite-coated implants are biocompatible that
11 they will form a bond with bone and better than their counterparts
12 due to its chemical similarity to bone mineral. Plaintiff is
13 further informed and believes and thereon alleges the FDA
14 determined that the Calcitite is different from standard or
15 natural HA and does not do all that CALCITEK claims it does as set
16 forth herein.

17 124. On information and belief, Plaintiff alleges that prior
18 to Plaintiff being treated by Defendants, DR. EVASIC, SCRIPPS
19 IMPLANT DENTISTRY EDUCATION & RESEARCH CENTER, DR. AIRES, CREATIVE
20 CUSTOM DESIGN, CUTRI, MAW, & BERGER, RALPH B. MAW D.D.S, and DOES
21 1-30 and each of them and continuing throughout her treatment with
22 Defendants, disseminated or caused to be disseminated public
23 communications, as defined by California Business and Professions
24 Code Section 651, containing false, fraudulent, misleading, and/or
25 deceptive statements and/or claims as follows: (1) DR. EVASIC
26 claimed he was the director of "SCRIPPS IMPLANT DENTISTRY
27 EDUCATION & RESEARCH CENTER" when neither DR. EVASIC nor "SCRIPPS
28

1 IMPLANT DENTISTRY EDUCATION & RESEARCH CENTER" are affiliated,
2 directly or indirectly, with any of the internationally acclaimed
3 health care facilities located in La Jolla, California known as
4 the Scripps Research Institute, The Scripps Clinic and Research
5 Foundation, or the Scripps Institutions of Medicine and Science.

6 (2) Each of the defendant dentists and professional corporations
7 held themselves out to be specialists in dental implantology and a
8 member of "American Academy of Implant Dentistry" and/or American
9 Academy of Oral Implantology" when dental implantology is not
10 recognized in the State of California as a specialty; this fact
11 was first learned by Plaintiff in November of 1997.

12 125. Plaintiff is informed and believes and thereon alleges
13 that Defendants, and each of them, disseminated or caused to be
14 disseminated each of these false, fraudulent, misleading and/or
15 deceptive statements (as herein alleged) and/or claims for the
16 purpose of inducing, directly or indirectly, the following: (1)
17 the rendering of dental services; and/or (2) to circumvent the
18 federal regulations regarding FDA approval; and/or (3) to prevent
19 Plaintiff from learning that the products implanted in her mouth
20 were not FDA approved.

21 126. Plaintiff did rely on the misrepresentations set forth
22 herein and each of them were substantial factors in inducing
23 Plaintiff to: (1) consult with Defendants, and/or (2) begin
24 treatment with Defendants, and/or (3) continue treatment with
25 Defendants, and/or (4) provide the opportunity to for Defendants
26 to implant CALCITEK products in her mouth, and/or (5) pay monies
27 for dental/medical services and CALCITEK products, and/or (6) to

1 believe that antibiotic treatment of the infections would
2 eventually cure Plaintiff's problem, and/or (7) delay in removing
3 CALCITEK implants from her mouth, (8) delay in obtaining proper
4 medical care, and/or (9) prevent Plaintiff from obtaining proper
5 dental/medical care since she can no longer afford it, and/or (10)
6 delay in discovering all that was done to her and implanted into
7 her jaw, and/or (11) delay in seeking to investigate the issue of
8 FDA approval, and/or (12) believe that the CALCITEK products
9 implanted in her mouth were FDA approved, and/or (13) delay
10 Plaintiff's learning the truth regarding FDA approval of the
11 medical devices implanted in her jaw, and/or (14) delay in suing
12 CALCITEK.

13 127. On information and belief, Plaintiff alleges that had
14 Plaintiff known the truth, she would have: (1) never consult with
15 Defendants, and/or (2) never begun treatment with Defendants,
16 and/or (3) never would have provided the opportunity for
17 Defendants to implant CALCITEK products in her mouth, and/or (4)
18 would have terminated treatment with Defendants before she did,
19 and/or (5) never paid monies for their dental/medical services and
20 never have paid monies for the CALCITEK products, and/or (6) not
21 been satisfied with antibiotic treatment for as long as she did,
22 and/or (7) not delayed in removing CALCITEK implants from her
23 mouth, (8) not delayed in obtaining proper medical care, and/or
24 (9) obtained proper medical treatment sooner than she did, and/or
25 (10) not delayed as long in discovering all that was done to her
26 and implanted into her jaw, and/or (11) not delayed in seeking to
27 investigate the issue of FDA approval, and/or (12) never have
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1 believed that the CALCITEK products implanted in her mouth were
2 FDA approved, and/or (13) not delayed in learning the truth
3 regarding FDA approval of the medical devices implanted in her
4 jaw, and/or (14) not delayed in suing CALCITEK.

5 128. Plaintiff is informed, believes and thereon alleges that
6 had Plaintiff known that CALCITEK's products were not
7 "substantially equivalent" or not FDA approved, she would have
8 never permitted CALCITEK products to be implanted in her mouth.

9 129. Plaintiff is informed, believes and thereon alleges that
10 before the subject devices were implanted in Plaintiff's mouth,
11 Defendants had actual knowledge they would cause injuries since:
12 (1) Defendants knew the composition of the medical devices were
13 made up of alloys and percentages of certain alloys that the FDA
14 advised against and which violated the Good Manufacturing
15 Practices, (2) Defendants knew the subject devices were not FDA
16 approved, and (3) Defendants knew similar devices had been
17 ~~rejected by the FDA and withdrawn from the market because of~~
18 injuries they had caused.

19 130. On information and belief, Plaintiff alleges that
20 Defendants concealed the information, as alleged herein, from her
21 and Plaintiff, who was unaware of these dangers, would not have
22 permitted the implantation of the medical devices and/or would
23 have removed the CALCITEK medical devices sooner and/or sought
24 proper medical treatment sooner had Defendants properly warned of
25 the above facts and/or properly warned her of the risks associated
26 with the subject devices.

27 131. Plaintiff was unaware of the falsity of Defendants'
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1 representations and believed them to be true and her reliance on
2 Defendants' misrepresentations was justifiable because Plaintiff
3 trusted Defendants, especially since Plaintiff was unlearned in
4 dental implants and had a complete dependence on and trust in
5 Defendants for the information regarding Defendants' knowledge,
6 training, credentials, affiliations, and skill as claimed
7 specialists in dental implants.

8 132. Plaintiff's reliance on Defendants' misrepresentations
9 was further justifiable because of the following: (1) the subject
10 matter is highly technical and difficult to understand by a lay
11 person, (2) the FDA refused to assist Plaintiff at first and
12 referred her to CALCITEK, (3) CALCITEK misrepresented to Plaintiff
13 that the medical devices were all FDA approved, (4) Plaintiff's
14 dentists, who were working with CALCITEK, also misrepresented that
15 the subject devices were FDA approved, and (5) it has been
16 extremely difficult for Plaintiff to learn as much as she has
17 regarding what Defendants implanted in her mouth. Plaintiff is
18 informed, believes and thereon alleges that because Calcitite
19 shows up as bone on an x-ray, the only thing Plaintiff can do is
20 to undergo extensive surgery on both jaws in order to fully see
21 what Defendants have done and this is an impossible task if you do
22 not have the money or insurance as is the case here.

23 133. Plaintiff did not learn of Defendants' fraud as alleged
24 herein until May 1999; after she read through and assimilated four
25 volumes of highly technical information she located in a recent
26 case filed in Orange County. Plaintiff was not at fault for
27 failing to discover the information for herself prior to this
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1 date.

2 134. As a direct result of the fraudulent misrepresentations
3 of Defendants, and each of them, Plaintiff paid Defendants monies,
4 and has incurred and will continue to incur dental medical,
5 hospital, psychiatric and related expenses, all to her special
6 damage in an yet unascertained amount; Plaintiff will seek leave
7 to amend this complaint to state the true amount when ascertained.

8 135. As a further direct result of the fraudulent
9 misrepresentation of Defendants, and each of them, Plaintiff has
10 sustained injury to her health, strength, and activity, all of
11 which injuries have caused, and continue to cause, Plaintiff great
12 mental, physical, and nervous pain and suffering. Plaintiff is
13 informed, believes and thereon alleges that such injuries will
14 result in some permanent disability to her. As a result of such
15 injuries, Plaintiff has sustained general damages as a yet
16 unascertained amount; Plaintiff will seek leave to amend this
17 complaint to state the true amount when ascertained.

18 136. The aforementioned conduct of the Defendants was done
19 willfully, maliciously, with conscious disregard of the rights and
20 well-being of Plaintiff. The conduct is also a intentional
21 misrepresentation, deceit, or concealment of a material fact known
22 to the Defendants with the intention on the part of the
23 Defendants, and each of them, of thereby depriving Plaintiff of
24 property or legal rights or otherwise causing injury, and was
25 despicable conduct that subjected Plaintiff to a cruel and unjust
26 hardship in conscious disregard of Plaintiff's rights, so as to
27 justify an award of exemplary and punitive damages.

28

1 137. This action was filed within 3 years of discovering the
2 fraud herein alleged against each of the Defendants.

3 WHEREFORE, Plaintiff demands judgment as set forth below.

4 III

5 THIRD CAUSE OF ACTION

6 (NEGLIGENCE)

7 138. Plaintiff incorporates paragraphs 1-102, 105-113, and
8 their respective facts and allegations into this cause of action.

9 139. This cause of action is against all Defendants.

10 140. Plaintiff is informed, believes, and thereon alleges,
11 that each of the Defendants failed to exercise due care, under the
12 circumstances, toward Plaintiff in doing or failing to do the acts
13 or omission as alleged above, which include but not limited to the
14 following: (1) failing to warn Plaintiff of the dangers of
15 Calcitite and Calcitite-coated products, and/or (2) failing to
16 obtain FDA approval prior to marketing the medical devices that
17 ~~are implanted in Plaintiff's jaw,~~ and/or (3) negligently
18 certifying in their 510(k) submissions that the devices were
19 "substantially equivalent" to those devices marketed prior to May
20 28, 1976, as herein alleged, and/or (4) failing to promptly
21 respond to Plaintiff's inquiries regarding their products and
22 failing to provide her with the correct information that the
23 CALCITEK products in her mouth are not FDA approved, and/or (5)
24 negligently making advertising claims that were not substantiated
25 to the FDA and representing the subject devices were safe and fit
26 for their intended use when they are not, and/or (6) the Defendant
27 dentists and dentist corporations failed to disclose to Plaintiff
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1 their ownership of CALCITEK stock, being a research clinician for
2 CALCITEK and/or the alter ego of CALCITEK, and/or (7) failing to
3 properly diagnose and medically treat Plaintiff, and/or (8)
4 holding themselves out as specialists in implantology when that
5 specialty is not even recognized by the State of California.

6 141. Plaintiff is informed, believes, and thereon alleges,
7 that each of the Defendants made the representations alleged
8 herein with no reasonable ground for believing that the
9 representations were true and Defendants, and each of them, made
10 the representations with the intent to induce Plaintiff to rely on
11 them in the ways that she did also set forth herein.

12 142. Plaintiff is informed, believes, and thereon alleges,
13 that each of the Defendants failed to make a full and fair
14 disclosure and suppressed and concealed from Plaintiff the facts
15 herein alleged to be withheld or concealed. Defendants, and each
16 of them, made the failures to disclose and suppressions of
17 information herein alleged with the intent to induce Plaintiff to
18 act in the manner herein alleged in reliance thereon, and with the
19 intent to prevent Plaintiff from doing the things herein alleged.

20 143. The Defendants were negligent in doing the foregoing
21 acts and omissions, since they fell below the reasonable standard
22 of care that they owed to Plaintiff.

23 WHEREFORE, Plaintiff demands judgement as set forth below.

24 IV

25 FOURTH CAUSE OF ACTION

26 (BREACH OF A FIDUCIARY DUTY)

27 144. Plaintiff incorporates paragraphs 1-102, 105-113, 117-

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1 137, 140 and their respective facts and allegations into this
2 cause of action.

3 145. This cause of action is against all Defendants except
4 CALCITEK and MR. RILEY.

5 146. Plaintiff is informed, believes and thereon alleges that
6 Defendants, at all times mentioned herein, a fiduciary
7 relationship with Plaintiff as a medical provider does to a
8 patient and was acting in the course and scope of such at all
9 times mentioned herein as the result of entering into an written
10 contract to provide dental services for the amounts alleged
11 herein.

12 147. The foregoing acts and omissions breach the fiduciary
13 duty owed to Plaintiff.

14 WHEREFORE, Plaintiff demands judgement as set forth below.

15 V

16 FIFTH CAUSE OF ACTION

17 (DENTAL MALPRACTICE)

18 148. Plaintiff incorporates paragraphs 1-102, 105-113, 140,
19 146 and their respective facts and allegations into this cause of
20 action.

21 149. This cause of action is against the all Defendants
22 except CALCITEK and MR. RILEY.

23 150. From and after the time of the employment, Defendants,
24 and each of them, so negligently failed to exercise the proper
25 degree of knowledge and skill in examining, diagnosing, treating,
26 and caring for Plaintiff that she was caused to suffer the
27 injuries and damages hereinafter alleged.

28

1 151. As a legal result of the negligence of Defendants, and
2 each of them, Plaintiff has sustained injury to her health,
3 strength, and activity, all of which injuries have caused, and
4 continue to cause Plaintiff great mental, physical, and nervous
5 pain and suffering. Plaintiff is informed, believes and thereon
6 alleges that such injuries will result in some permanent
7 disability to her. As a result of such injuries, Plaintiff
8 sustained general damages as a yet unascertained amount; Plaintiff
9 will seek leave to amend this complaint to state the true amount
10 when ascertained.

11 152. As a further legal result of the negligence of
12 Defendants, and each of them, Plaintiff has incurred and will
13 continue to incur dental, medical, hospital, and related expenses,
14 all to her special damage in an yet unascertained amount;
15 Plaintiff will seek leave to amend this complaint to state the
16 true amount when ascertained.

17 153. Plaintiff is informed, believes and thereon alleges that
18 a violation of the Act gives rise to a presumption of negligence
19 and that implanting medical devices, which are not approved by the
20 FDA, must be below the standard of care.

154. On information and belief, Plaintiff further alleges that the professional negligence herein alleged can be evaluated based on common knowledge, without expert testimony, since scientific enlightenment is not essential for determination of an obvious fact.

26 WHEREFORE, Plaintiff demands judgement as set forth below.

27 VI

1 SIXTH CAUSE OF ACTION

2 (GROSS NEGLIGENCE)

3 155. Plaintiff incorporates paragraphs 1-102, 105-113, 117-
4 135, 140, 146, and their respective facts and allegations into
5 this cause of action.

6 156. This cause of action is against all Defendants.

7 157. In doing the things herein alleged, Defendants acted
8 willfully and with the intent to cause injury to Plaintiff.
9 Defendants were therefore guilty of malice and/or oppression
10 and/or fraud in conscious disregard of Plaintiff's rights, thereby
11 warranting an assessment of punitive damages in the amount
12 appropriate to punish Defendants and deter others from engaging in
13 similar conduct.

14 WHEREFORE, Plaintiff demands judgement as set forth below.

15 VII

16 SEVENTH CAUSE OF ACTION

17 (NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS)

18 158. Plaintiff incorporates paragraphs 1-102, 105-113, 140,
19 146 and their respective facts and allegations into this cause of
20 action.

21 159. This cause of action is against all Defendants.

22 160. The foregoing acts and omissions were negligent,
23 extreme, outrageous and the Defendant knew or should have known
24 that they were substantially likely to cause Plaintiff to suffer
25 severe injury, mental anguish, and severe emotional and physical
26 distress and injury as mentioned herein, and were made when each
27 of the Defendants knew or should have known they were
28

1 substantially likely to have such effect.

2 161. As a direct, proximate, and natural result of
3 Defendants' acts and omissions, Plaintiff suffered severe
4 injuries, shock, pain, extreme mental anguish, headaches, anxiety,
5 stress, fright, and severe emotional and physical distress and
6 injury as mentioned herein, all to Plaintiff's damage.

7 WHEREFORE, Plaintiff demands judgment as set forth below.

8 IX

9 NINTH CAUSE OF ACTION

10 (INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS)

11 162. Plaintiff incorporates paragraphs 1-102, 105-113, 117-
12 135, 140, 146 and their respective facts and allegations into this
13 cause of action.

14 163. This cause of action is against all Defendants.

15 164. The foregoing acts and omissions were intentional,
16 malicious, outrageous, and the Defendants knew or should have
17 known that they were substantially likely to cause Plaintiff to
18 suffer severe injury, mental anguish, and severe emotional and
19 physical distress and injury as mentioned herein, and were made
20 when each of the Defendants knew or should have known they were
21 substantially likely to have such effect.

22 165. As a direct, proximate, and natural result of
23 Defendants' acts and omissions, Plaintiff suffered severe
24 injuries, shock, pain, extreme mental anguish, headaches, anxiety,
25 stress, fright, and severe emotional and physical distress and
26 injury as mentioned herein, all to Plaintiff's damage.

27 WHEREFORE, Plaintiff demands judgment as set forth below.

28

X

TENTH CAUSE OF ACTION

(STRICT LIABILITY -- Failing To Follow FDA Regulations & Products Liability)

166. Plaintiff incorporates paragraphs 1-102, 105-113 and their respective facts and allegations into this cause of action.

167. This cause of action is against all Defendants.

168. On information and belief, Plaintiff alleges that each of the Defendants are strictly liable on the basis of products liability for: (1) their failure to warn Plaintiff of the dangers associated the medical devices she received and purchased, (2) improper manufacture, (3) failure to perform safely as an ordinary patient would expect the subject medical devices to perform.

169. Plaintiff is informed, believes and thereon alleges that Calcitite and Calcitite-coated products, which were implanted into Plaintiff's mouth, contained manufacturing defects and unreasonably dangerous defects and unreasonably dangerous to foreseeable users at the time of its sale to Plaintiff.

170. On information and belief, Plaintiff alleges that CALCITEK failed to follow the manufacturing protocol approved by the FDA resulting in a manufacturing defect and CALCITEK did not comply with all the federally imposed manufacturing recommendations and requirements and Defendants knew or should have known the patients or consumers, such as Plaintiff, would not ordinarily inspect for such defects and such faults rendered the medical devices unreasonably dangerous to the life, health and safety of those using it. The deficiencies in the medical devices

1 proximately caused Plaintiff's injuries and damages as set forth
2 herein.

3 WHEREFORE, Plaintiff demands judgment as set forth below.

4 XI

5 ELEVENTH CAUSE OF ACTION

6 (BREACH OF WARRANTY)

7 171. Plaintiff incorporates paragraphs 1-102, 105-113, 140,
8 146, 150-154 and their respective facts and allegations into this
9 cause of action.

10 172. This cause of action is against all Defendants except
11 CALCITEK and MR. RILEY.

12 173. Defendants had expressly and impliedly warranted that
13 Calcitite and Calcitite-coated products were fit for its intended
14 use without causing physical injury but the product was defective,
15 dangerous and unsafe.

16 WHEREFORE, Plaintiff demands judgment as set forth below.

17 ~~XII~~

18 TWELFTH CAUSE OF ACTION

19 (BREACH OF CONTRACT AND COVEN. OF GOOD FAITH AND FAIR DEALING)

20 174. Plaintiff incorporates paragraphs 1-102, 105-113, 117-
21 135, 140, 146, 150-154 and their respective facts and allegations
22 into this cause of action.

23 175. This cause of action is against all Defendants except
24 CALCITEK and MR. RILEY.

25 176. In doing the foregoing acts and omissions Defendants
26 breached the written contracts each had with her by failing to
27 perform all their conditions as mentioned herein.

28

1 177. Also in doing the foregoing acts and omissions
2 Defendants, and each of them breached the covenant of good faith
3 and fair dealing with Plaintiff.

4 178. As a direct and proximate result of Defendants' breach
5 of contract, Plaintiff has suffered serious injury and is entitled
6 to recover the following: (a) all reasonable foreseeable economic
7 losses, (b) costs incurred by Plaintiff in establishing this claim
8 against Defendants, according to proof and (c) interest at the
9 legal rate.

10 WHEREFORE, as to all causes of action against Defendants and
11 each of them, the Plaintiff prays for relief as follows:

12 1. For general damages in an amount to be proven at the
13 time of trial;

14 2. For dental, medical, and related expenses, past, present
15 and future, according to proof at the time of trial;

16 3. For compensatory damages;

17 4. For interest on all damages as allowed by law;

18 5. For exemplary and punitive damages in an amount
19 according sufficient to punish Defendants, and each of them;

20 6. For costs of suit incurred herein; and

21 7. For other and further relief as the Court may deem just
22 and proper.

23 Dated: July 15, 2001

24
25 

26 Plaintiff,
27 Mary Masters
28